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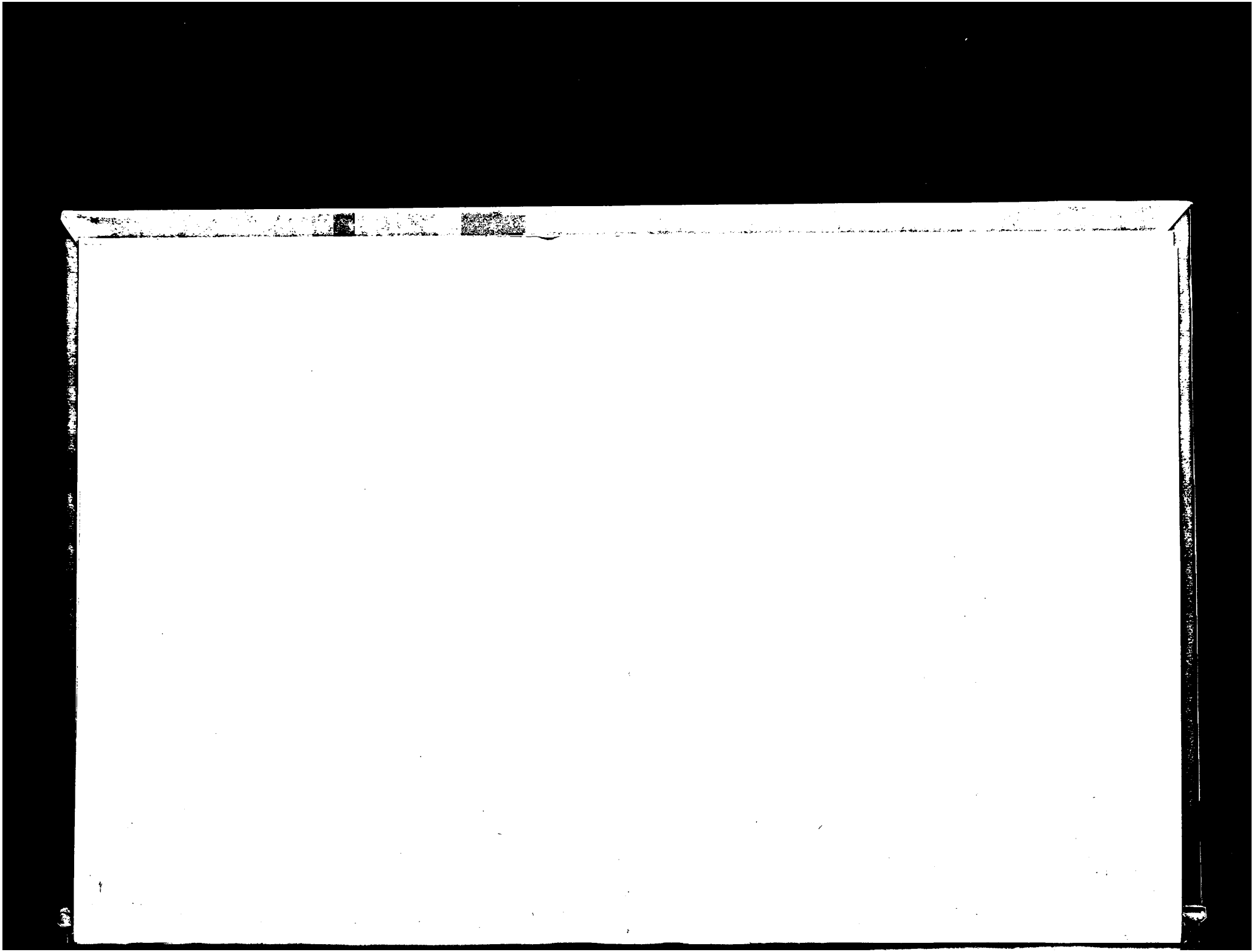
Project Paper NUMBER 82

Assuring the quality of medical practice

An international comparative study

TIMOTHY S JOST



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Typeset by J&L Composition Ltd, Filey, North Yorkshire
Printed in England by Hollen Street Press
Distributed by Bailey Distribution Ltd

ISBN 1 85551 051 0

I. Introduction

This report grew out of the belief, which inspires comparative research generally, that there are lessons to be learned from the experience of others. Here the author's perspective was initially that of an American, and the problem investigated was how government might go about assuring the quality of medical care. This is a topic of great current importance in the United States. The projected 1990 budget for the Medicare Peer Review Organization (PRO) Programme, which has increasingly focused on quality review, is $290 million. Calls for strengthening state professional disciplinary efforts are frequent (AARP 1987; Kusserow et al. 1987). These disciplinary programmes are aided by a new federal data bank to which all malpractice settlements and judgments and hospital and professional disciplinary actions must be reported (Bierig and Portman 1988). Medical malpractice suits based on allegations of poor quality medical care are becoming more frequent and involve ever higher sums of money. It is not clear, however, that all of this activity and expense is significantly improving the quality of American medical care.

The initial hypothesis on which this study was begun was that governments of European countries, which have been financing medical care through public or quasi-public means for decades, would have developed more efficient and effective means of assuring the quality of medical care from which the United States could learn. Surely, it was posited, European countries would have an interest in making certain that the quality of the medical care they purchase is of high quality, and would have developed mechanisms for monitoring and policing the quality of medical care.

As the study progressed, however, it became clear that Europe has not yet proceeded down the path of external quality review that the US is currently travelling, and thus could not lead in that direction. What became strikingly apparent, however, was how much Europeans could potentially learn from each other. For, in fact, there is a great deal of current activity in Europe with respect to assuring the quality of physician practice and hospital care and much of it is proceeding in similar directions.

Target 31 of the 'Strategy for Health for All by the Year 2000' of the Regional Committee for Europe of the World Health Organization – the nearest approximation of an official pan-European health policy statement – reads: 'By 1990, all Member States should have built effective mechanisms for ensuring the quality of patient care within their health care systems' (WHO 1985, p. 116). Though no country has yet reached this goal, West Germany has adopted legislation, effective 1 January 1989, mandating quality assurance efforts in both the ambulatory and institutional sectors (SGB V, ss. 135–137); Belgium has enacted a hospital law,

effective 6 May 1988, requiring 'appropriate measures for the improvement and permanent evaluation of the quality of medicine at the hospital' (AR, 7 August 1987, art. 124); and medical audit is a key part of Britain's recent white paper proposing reconstruction of the National Health Service (Department of Health 1989a; 1989b).

The quality assurance strategies reflected by these developments are quite different from those currently being pursued in the United States. They depend on professionals reviewing one another's work rather than on government- or insurer-led quality review; they are based on educational rather than punitive interventions; they are usually focused on particular problem areas rather than on the performance of individuals. But, though the programmes of European nations differ from American approaches, they share much in common among themselves.

Given this similarity, it was striking how little awareness many of the experts I interviewed seemed to have of quality assurance developments in other European countries. It became clear, therefore, that this report had more to contribute to a European than to an American audience; that the most useful purpose it could serve would be to facilitate communication among the countries on which it focuses to assist them in going forward together rather than independently. To this goal, then, this paper is primarily directed.

Nevertheless, comparison between the American and European agendas will not be abandoned altogether. Ultimately the question must be asked whether the path Europe is currently following will prove satisfactory – whether Europe will be able to avoid external intervention to assure the quality of medical care such as is increasingly common in the United States. Consideration must also be given to the question of whether the United States should learn from Europe; indeed some are now beginning to ask whether we left too quickly the path Europe is still travelling (Berwick 1989). These questions will also be addressed in concluding remarks.

II. Method and scope

This report is concerned with efforts to assure quality in medical care. More specifically, it is focused on quality assurance efforts affecting care provided by doctors and hospitals (and to a lesser extent nursing homes). This is not to deny important developments in quality assurance with respect to the quality of nursing, dentistry, pharmaceuticals or other health care professionals or products, but rather to focus research on those medical care professionals and providers that consume the most resources and probably have the greatest effect on patients, for good or for harm.

'Quality assurance' here refers to programmes that set quality standards, assess performance of professionals or institutions with respect to these standards, and attempt corrective action when the divergence from standards exceeds acceptable levels. Such standards may be explicit or implicit. Corrective actions may be informational, educational, or punitive. Reflecting its origins in a search for cognates to American regulatory mechanisms this report is particularly concerned with the regulatory or managerial interventions of governments or insurers. These include traditional administrative regulatory programmes, such as professional or institutional licensing; judicial oversight through negligence litigation; complaint investigation programmes of socialised health systems; and insurance review programmes of traditional social insurance systems. The penultimate section of the report addresses more recent developments, including medical audit programmes. Medical audit is defined narrowly to include programmes in which doctors review each other's work for educational or informational purposes.

To discuss quality assurance, one must define what is meant by quality. European commentators tend to define health care quality broadly to cover scientific-technical knowledge and skills, effectiveness, adequacy, efficiency, acceptability to patients and, under some definitions, also accessibility and equity (Blanpain 1985; Maxwell 1984; Shaw 1986a; Towell 1987; Vouri 1982). The term can, in fact, be defined so broadly as to include all concerns of health policy, all desiderata in health care. This report works with a somewhat more narrow definition, more common in the United States, which focuses on the technical appropriateness and efficacy and the relational and communicational acceptability of care. Concerns of equity and economy are more tangential to its concerns.

This study examines quality assurance in four European countries: Sweden, the Federal Republic of Germany, Belgium and England.[1] These four were chosen, in large part, because they represent a range of approaches to health care system organisation. To simplify complexities that will presently be more fully explicated, in Sweden and England health care is both provided and paid for by the government; in Belgium and West Germany health care is privately provided (though many hospitals are publicly owned) and financed through mandatory quasi-public

insurance. These countries illustrate, therefore, a range of possible approaches to the organisation and regulation of health care.

The study is based on interviews with nearly 80 experts on the relevant health care systems (see list following report). It also draws on an extensive review of English language literature and a more selective review of German and French language literature on medical care quality assurance in the subject countries. It begins by describing the health care delivery and financing systems of these countries. It then proceeds to examine the means these countries are using or developing for medical care quality assurance: professional education and licensing, professional discipline, review of patient complaints, insurance review, institutional inspection, private litigation, and various quality assurance and medical audit programmes. It concludes by reflecting on the future of health care quality regulation in Europe.

III. The context of quality assurance: health care systems compared

Sweden

Provision and financing of health care in Sweden is regarded as primarily a task for the public sector. The vast majority of health care is provided by Sweden's 23 county councils (Landsting) and three large municipalities which are not part of county council areas (Gothland, Gothenberg and Malmo). In 1984 the county councils operated 98 acute-care hospitals and employed 18,300 doctors in hospitals and health care centres (Swedish Planning and Rationalisation Institute (SPRI) 1987b). Sweden also has a small, but growing, private health care sector. There are only two private hospitals in Sweden, but about 250 private nursing homes (Rosenthal 1986).

Compared to other countries, Sweden tends to rely more heavily on hospital care and, in particular, on large hospitals (Borgenhammer 1984). In 1983 Sweden had 14 medical care beds per 1000 population, compared to 8.1 beds per 1000 in the UK, 9.5 in Belgium, and 11.1 in the FRG (OECD 1987). Fifty-three per cent of visits to doctors in Sweden take place at hospitals, 30 per cent in the public primary care system, and 17 per cent in the private sector (Swedish Institute 1987). On the other hand, the primary care sector is exceptionally well organised, with the country divided into primary care districts of 5000 to 50,000 inhabitants, served by 800 health care centres (Saltman 1988; SPRI 1987b; Swedish Institute 1987). At these health care centres, groups of district physicians and nurses provide both general practice and specialist medical treatment and preventive care (Swedish Institute 1987). Virtually all health sector employees are unionised, with most employees belonging to three large unions representing doctors and administrators, nurses and physiotherapists, and support personnel.

Sweden has had a comprehensive national health insurance system since 1955 (Saltman 1988). About two-thirds of the cost of the health insurance system is financed by the county councils from county taxes. Most of the rest is paid for by the national government, financed in part by employer contributions and in part by general taxes (Hellner 1985). Patients pay moderate co-payments to the county council for physician visits and pharmaceuticals and pay for up to 60 per cent of dental care (Swedish Institute 1987). Sweden spends a relatively high proportion of its resources on medical care. In 1987 it spent 9 per cent of its GNP on health care ($1233 per capita), compared to 6.1 per cent ($758 per capita) in the UK, 7.2 per cent ($879 per capita) in Belgium, and 8.2 per cent ($1093 per capita) in the FRG (Schieber and Poullier 1989).[2] Growth in public health care expenditures in Sweden in recent years, however, has not been as dramatic as growth in other countries (SPRI 1987; Rosenthal 1986), indeed the percentage health consumption of GNP has dropped from a high of 9.5 per cent in 1980 (Schieber and Poullier 1989).

The predominant trend of Swedish health policy over the last two decades has been towards decentralisation, with the county councils taking primary responsibility for medical care since the Health and Medical Services Act of 1983 (Ham 1988). The national role has been limited to adoption of broad national frame laws that set general goals for the health care system, general supervision by the National Board of Health and Welfare, and research and development assistance by SPRI (Ham 1988). Very recently, however, concern has surfaced that decentralisation has gone too far, resulting in too great diversity among the counties. This concern has led to current proposals of the Ministry of Health to revitalise the National Board of Health, giving it additional information gathering and supervisory powers, including the creation of regional offices to facilitate closer oversight. On the whole, however, Sweden remains strongly committed to decentralised delivery and financing of health services.

England

In England, as in Sweden, medical care is publicly funded and provided. Indeed, the British National Health Service, which began in 1948, represents the first and most ambitious attempt by a Western nation to provide health care for its citizens as an entitlement rather than through an insurance programme.[3] Unlike Sweden, England has chosen a centrally organised and funded health care system. The NHS is subject to the Secretary of State for Health. Under a reorganisation currently under way, its operations will be headed by a NHS Management Executive Board, subject in turn to a NHS Policy Board, chaired and appointed by the Secretary of State for Health (DH 1989a) In managing the NHS, the Secretary of State works through 14 regional health authorities (RHAs), which currently have responsibility for planning, resource allocation, monitoring service provision, and direct provision of a few services (such as blood transfusion services). Under the regions are 192 district health authorities (DHAs), which determine policies and priorities for and monitor the performance of the hospitals that provide medical care (Ham 1985; Levitt and Wall 1984; NAHA 1985a).[4] General practitioners are not employees of the NHS, but rather hold independent contracts with 90 family practitioner committees (FPCs), which are appointed by the Secretary of State (Ham 1985; Levitt and Wall 1984).[5] Finally, community health councils (CHCs) in each district are responsible for taking a watchdog role, representing consumer interests (Levitt and Wall 1984). The vast majority of the funding of the NHS comes from general taxation (86 per cent) with smaller shares coming from insurance contributions (11 per cent) and patient charges (3 per cent) (1983-4 figures, Ham 1985).

Although separation of primary and specialist care is characteristically

European, England carries this principle even further than most of the other nations in this study. Every patient is England is attached to a general practitioner, who acts as a gatekeeper for all specialist and hospital care. GPs are responsible for about 90 per cent of the patient contacts of the NHS (Allen 1984). As in Sweden (but in contrast to Belgium or the FRG) most English GPs work in group practices (Allen 1984). General practitioners are currently paid under a complex formula including a basic practice allowance (adjusted for seniority and to provide incentives to practice in underserved areas), a per patient capitation fee, and a fee-for-service component covering special services such as vaccination or contraception (Levitt and Wall 1984). The current government, however, is proposing to rely much more on capitation fees for paying GPs (DH 1989a). It would also allow larger practices, at their option, to manage practice budgets that would cover the costs of outpatient care, diagnostic tests, prescribing costs, some inpatient care for their patients, as well as some practice costs (DH 1989a). Under this system, GPs would be allowed to use 'profits' generated from these budgets to improve their practices and thus ultimately – if 'improved' practices attracted more patients – to increase their capitation payments.

Most specialists in England are employees of the NHS and work as 'consultants' in its hospitals. They are paid based on schedules negotiated at the national level, supplemented by merit awards. The long course of specialist training in England (see Section IV below) assures that these doctors are assisted by a large number of junior doctors of different grades of experience. Up to now consultants have effectively controlled important decisions in NHS hospitals, particularly with respect to resource allocation (Ham 1985; Ham 1988; Klein 1989). In recent years, initiatives by the government have tried to strengthen the management role in the hospital (DHSS 1983a; DH 1989a). Recent government proposals supplement this strategy with another, suggesting that hospitals should be permitted to opt out of NHS management structures to become self-governing, free to make their own 'profits' or absorb their own losses, substituting the discipline of the market for the discipline of management (DH 1989a).

The ultimate effect of the current government's reorganisation proposals may be to separate the service purchasing and service provision functions of the NHS. If current proposals are implemented, the DHAs (and budget-holding GPs) would be encouraged to provide services to patients in their districts not only through hospitals under DHA control, but also by purchase from self-governing hospitals, hospitals in other districts, or from the private sector (DH 1989a). This could ultimately make the NHS look much more like an insurer, and replace current problems of management with problems of regulation and contract enforcement.

The private sector in England is still small but is growing, encouraged by the current government. Nine per cent of the population of the UK

currently supplement their NHS coverage with private health insurance, and 17 per cent of elective surgery in England is now provided in the private sector (DH 1989a). The private sector plays a particularly important role in providing hospice and nursing home care.

England spends far less of its GNP on health care than do the other countries covered by this study. The growth of its health care expenditures has been effectively limited by its centrally controlled fixed budget, which has been held to very modest increases in recent years (Webster 1989).

The Federal Republic of Germany

The organisation of health care delivery and financing in the Federal Republic of Germany presents a striking contrast to Sweden and England. Though the FRG boasts the oldest national health insurance programme in the world (it was initiated by Bismark in 1883), both medical care delivery and financing in Germany take place largely in the private or, perhaps more accurately, quasi-public, sector.[6] The ambulatory care sector in the FRG is entirely private; nearly half the hospital beds in the FRG are private or voluntary, and health insurance, though compulsory for most workers, is administered by self-governing quasi-public entities.

Two themes encountered recurrently in health policy in the FRG are federalism and 'Selbstverwaltung' (self-governance). The FRG is composed of 11 states (Länder), which take primary responsibility for many aspects of health policy. Physician licensure and discipline are regulated at the state level, as are most matters pertaining to hospitals. Indeed, about half the hospital beds in Germany are controlled by the states or (more commonly) by local government, and issues of financing and regulation of hospitals are jealously preserved from federal control (Beske 1988; Webber 1988). The federal government's role is by and large limited to the adoption of laws which set the framework within which the states operate, though it takes a more active role in setting policy for the health insurance system and regulating basic medical education.

Self-governance is an even more important theme. The German health care system is organised into quasi-public guild-like corporate structures (Bergmann-Krauss 1986; Ridder 1986; Stone 1980). All doctors must be members of the physician chamber (Ärztekammer) of their state. The chambers are self-governing bodies, whose boards are elected by their members. They are responsible for professional, ethical and disciplinary matters, as well as postgraduate and continuing education. Most physicians in ambulatory practice are also members of one of the FRG's 18 Kassenärztliche Vereinigungen, or organisations of insurance fund doctors (KVs), again headed by boards elected by their membership. The KVs negotiate on behalf of the doctors with the insurance funds (Beske 1988; Stone 1980). The mandatory sickness insurance funds

(gesetzliche Krankenkassen or Ersatzkassen) are established by law but administered by boards elected by those who fund them: both employees and employers for the Krankenkassen and employees only for the Ersatzkassen. The entire system operates with relatively little regulatory interference or financial participation from government (In 1980, taxes financed only 14.3 per cent of the costs of health services in Germany (Eichhorn 1984).)

Another characteristic of the German health system is the extent to which it relies on the ambulatory care sector for delivery of primary and specialist care. As in most European countries, there is little overlap between office-based and hospital physicians. Unlike many other countries, however, a high percentage of office-based doctors, about half, are specialists. It is common for a primary care doctor to refer a patient to an office-based specialist rather than to a hospital for specialist care or even surgery. Group practice has grown less rapidly in the FRG than in other countries, but laboratory partnerships permit office-based physicians direct access to expensive and sophisticated medical equipment (Eichhorn 1984).

Because statutory health insurance in Germany is tied to income and form of employment, its coverage is not universal (as in England or Sweden). It covers about 93 per cent of the population, however, including blue-collar workers, white-collar workers with incomes below a specified level (for 1989, 54,900 DM), retired persons, the unemployed and dependents of persons in these groups (Altenstetter 1987). The remaining 7 per cent of the population is by and large privately insured. A rather generous minimum benefit package is required of the mandatory sickness funds by law, including cash disability payments and coverage of most primary and hospital medical care, with modest co-payments for hospital care and drugs. Sickness fund members can generally choose to see any primary care physician who is a member of the insurance doctors' association, but can normally, except in emergencies, only be admitted to hospital with the referral of an office-based doctor.

Fees for doctors in office-based insurance practice are established through a complex process. The sickness funds and KVs negotiate both a relative value schedule for various kinds of physicians' services and a total cap on expenditures. The KVs then allocate the total funds available among their member doctors on a fee-for-service basis, considering the number of services each doctor has delivered and the relative value of those services (Stone 1980). Under this system, in which a doctor's share of the total pie depends in large part on the number of services he bills for, there is a temptation to bill for an excessive number of services. Thus the sickness funds and KVs have worked out a rather complex system of economic monitoring to catch doctors who attempt to game or defraud the system (see Section VII; Döhler 1987; Stone 1980).

Hospital capital costs are reimbursed by the state government.

Operating costs or user charges (including payments for physicians services received within the hospital) are reimbursed by the sickness funds through budgets set through negotiations between the sickness funds and hospitals (Altenstetter 1987). Doctors working within hospitals are generally employees whose salaries are negotiated collectively between their unions and the hospital organisations.

Health expenditures in Germany are rather high by European standards, measured by either share of GNP (8.2 per cent in 1987), or by per capita health expenditures ($1093 per year in 1987) (Schieber and Poullier 1989). Physicians incomes are also extraordinarily high, at 4.9 times the income of the average worker, compared to 1.8 in Belgium, 2.1 in Sweden, or 2.4 in the UK (1981 figures, OECD 1987). The growing cost of health care is a continuing concern, and was a major focus of recent health reform legislation.

Belgium

Of the health care systems studied here, that of Belgium relies most on the private sector and most closely resembles that of the United States. Most doctors, including general practitioners and specialists, work in private solo practice (Nys and Quaethoven 1984). Doctors generally have staff privileges at hospitals rather than being employed by them. The great majority of hospital beds (63 per cent) are in private, voluntary hospitals. Medical services are largely funded by quasi-private insurance companies.[7] Belgium thus represents the opposite end of the spectrum from the socialised health care systems of Sweden and England.

The divisions that characterise Belgium pervade the organisation of Belgium health care. The insurance company groups – Christian, socialist, liberal, professional, and neutral – reflect the political and economic divisions of Belgian society. Similarly, religious and political groups control many of the hospitals and other institutions that deliver health care services. The division in Belgium between the two great linguistic communities, the Walloon (French) and Flemish (Dutch) also appears repeatedly throughout the health care system (Nuyens 1986). The Order of Physicians, which regulates medical practice, for example, is divided at every level into French and Flemish councils.

Every resident of Belgium must belong to one of the 'mutualites' or sickness funds. In addition to a public auxiliary fund, there are five national unions of sickness funds, subdivided into 120 federations, which in turn group 1,649 local mutual benefit societies (NSIII 1982).[8] Sickness fund benefits are for the most part prescribed by law, although funds can charge a small additional contribution for extra benefits. Private employees are eligible for cash disability benefits and for health benefits. Members of the clergy, most public employees, and students are only eligible for health benefits. Self-employed persons are only required to be

insured for 'heavy risks' – which include hospitalisation, surgery and treatment for chronic conditions – and for cash benefits (NSIII 1982; Prims 1979). Most self-employeds, however, purchase supplemental coverage for ambulatory care.

The sickness fund system is funded and coordinated by the Institut National d'Assurance Maladie-Invalidité (INAMI), a body governed by representatives of the sickness funds and of other interest groups involved in medical care and its financing. The insurance programme is principally funded by employers' and workers' contributions, contributions from the self-employed, deductions from pensions, and state subsidies.

Most physicians, general practitioners and specialists, practise independently in a solo fee-for-service practice. Specialists will normally have staff privileges at one or more hospitals as well. Patients have unlimited free choice of doctors, and may go directly to a specialist without referral from a general practitioner (Nys and Quaethoven 1984). Physicians fees are set in accordance with an exhaustive nomenclatura of services negotiated between associations representing doctors and the sickness funds. Patients pay doctors directly for ambulatory care, and are then reimbursed by the sickness funds: 75 per cent of the set fee for consultations, 100 per cent for technical services.[9] As will be discussed in detail below (Section VII), the medical control service of INAMI examines the practices of doctors to make certain that they are billing for services only in compliance with the nomenclatura of services and the supervisory committee of INAMI also reviews computer profiles of the services provided by doctors to police excessive claims (NSIII 1982; Roemer and Roemer 1976).

About two-thirds of the hospitals in Belgium are private and non-profit, mostly owned by religious groups. Most of the remainder are owned by municipalities. Capital costs of hospitals are financed in part by the government. Operating costs are based on a per diem rate set by the government, with 25 per cent of the rate paid by the government and 75 per cent paid by the sickness funds (Nys and Quaethoven 1984). Hospitals are limited in the number of days they can bill by a fixed budget, however, and receive a reduced rate for days billed above that limit (see Hermesse 1986). Patients are responsible for a modest co-payment for hotel costs, and an often much larger payment for disposables and for pharmaceuticals, implants, and procedures not yet approved for reimbursement by the sickness funds. Doctors are paid directly by the funds independently for treatment in the hospital, but must contribute a significant share of their fees to the hospital.[10]

Health care costs in Belgium are moderate by European standards. The public share of health care costs, at 77 per cent is the lowest of any of the countries included in this study (Schieber and Poullier 1989).

IV. The foundations of professional competence: education and licensure

If one were to ask the average citizen of one of these four countries: 'what guarantees the quality of the care you receive when you seek medical treatment?' it is likely that the respondent would mention professional education and licensure. Each of the countries under review licenses and thus establishes educational and examination requirements for a variety of medical professionals. Because the EEC Treaty (which covers all the countries here under consideration except Sweden) guarantees mutual recognition of qualifications of 'medical and allied professions', these requirements look increasingly alike. But to what extent do these professional entry requirements actually assure the competence of professionals? To that question we first turn our attention, focusing on the qualifications of physicians.[11]

All four countries draw each year from a pool of aspirants to the medical profession far larger than the profession could accommodate. The high income levels, intellectually stimulating work, and opportunities to help others that characterise the medical profession, at least in the popular imagination, continue to attract a large number of intelligent and ambitious young men and, increasingly, women. Medical schools or national placement boards can thus afford to be very selective in choosing candidates. Germany, Sweden and England narrow the field at the point of admission to medical school, relying heavily on intellectual ability as demonstrated through examination scores and prior academic performance (Allen 1984; Borgenhammer 1984; Eichhorn 1984; Walton and Binns 1984). Germany also relies in part on a combination lottery/waiting list, and Sweden considers life experience as well as academic performance for older students. As most matriculated students in these countries finish the course and go on to practise medicine, this selection process plays a vital role in assuring the quality of medical practice. Belgium takes a different approach, permitting anyone who desires admission to medical school to have a go at it, but relying on a high attrition rate, about 60 per cent, to assure the quality of the final product (Albert et al 1989).

EC directives require that doctors complete a university course of training of six years or 5500 hours, including education in the basic sciences and clinical disciplines and supervised clinical experience. (EC Council Directive 75/363 art. 1). In England, medical instruction is supervised by the General Medical Council, and consists of five years of undergraduate medical instruction (including two years of basic sciences and three years of clinical education) followed by one year of general clinical training (GMC 1980; GMC 1987). The FRG has a very similar six year educational programme, including two years of basic science education, three years of clinical training, and one year of clinical experience. At intervals during this course of instruction, German

students take four multiple-choice examinations, which are uniform throughout the FRG, and at the end, an oral examination (BAO s. 3, subs. (4), Arnold et al 1982; Halbeck 1982; Renschler 1979). In Belgium the normal course of medical instruction takes seven years, including three years of basic science education leading to a 'candidature' and four years of clinical training leading to a 'doctorate' (Nys and Quaethoven 1984; Albert 1989). Two exams are given per year, and at each stage students may not advance until they have successfully passed the examination. Finally, Sweden, the one non-EC country studied, currently has a five and a half year programme leading to an MD degree, followed by a 21 month internship, leading to medical licensure (Borgenhammer 1984). Plans are currently underway in Sweden, however, to change to a task-oriented (as opposed to a time-limited) medical curriculum, which could take a longer or shorter period of time to complete than the current programme.

Possession of a licence to practise medicine does not, of course, necessarily mean that one can make a living at it, particularly in countries with a national health insurance programme. In Germany, for example, a doctor possessing an 'Approbation', or licence, must practise for an additional year under the tutelage of a KV physician before obtaining a 'Zulassung', or right to be reimbursed for outpatient care by the insurance system (SGB V s. 95). In England, general practitioners must complete three years training beyond licensure, including normally two years in a hospital and one year with a practising general practitioner, before they can obtain a contract to provide services for the NHS (Allen 1984).

In any event, most physicians currently pursue postgraduate education to obtain certification in general practice or in one of the other specialties. The broad outlines of specialist training are again governed by EC regulations in EC countries and are in many respects similar in all four countries (EC Council Directive 75/363, arts. 4, 5). There are noteworthy differences, however. Specialist training periods are shortest in Sweden, where they last from four to five and a half years, and longest in England, where most last from six to seven years (WHO Regional Office for Europe 1983). In Belgium a doctor seeking specialist certification must find a specialist trainer willing to accept him, and then get his individual training programme approved by the appropriate Flemish or French specialty chamber (Nys and Quaethoven 1984). The entire Belgian programme is run by the specialist societies and universities, with only broad guidance from the government. In Sweden specialist education is governed by the National Board of Health; in the FRG by the state physician chambers; and in England by the royal colleges subject to coordination by the General Medical Council (Smith 1989c). In Belgium there is no exam following specialist training; the FRG requires an oral exam; and in England candidates must endure oral, written and practical examinations (WHO Regional Office for Europe 1983).

Can these educational programmes be relied on to produce doctors who will consistently and reliably provide medical care of adequate quality? Certainly, there is much to be said for systems that first select the best and brightest, then impart to them a great deal of information under the pressure of repeated examinations, and finally provide supervised experience delivering care to actual patients, with increasing responsibility as the course progresses. But the process is certainly not above criticism.

First, the educational programmes of the individual countries each have their own peculiar weaknesses. The German programme has been criticised for its large class sizes and few undergraduate patient contact hours, and, above all, for its reliance on multiple choice exams which encourage rote learning (Halbeck 1982; Renschler 1979). The short specialist training periods required in Sweden, coupled with the 40 hour work week and 35 to 40 week work year in Sweden, has the potential for producing specialists with remarkably little experience in caring for patients (Smith 1981). On the other hand, the heavy reliance on junior doctors for patient care in England raises the spectre of service obligations crowding out education (Styles 1988).

Other criticisms apply more generally (WCME 1988; Ellis 1987; Horder et al 1984). First, fault is found with programmes for emphasising intellectual skills at the expense of interpersonal skills and, more narrowly, for stressing memory rather than critical and analytical skills. Medical training programmes, it is asserted, tend to rely on passive education rather than teaching active learning skills. Doctors are not trained adequately to be sensitive to the needs of their patients or aware of the larger context of health and disease. Training in primary care is generally neglected in favour of a focus on specialist training (Walton 1985). Educational programmes are criticised for being too short, crowded and fragmented; covering more information than in fact can be assimilated; and leaving inadequate time for reflection, integration and maturation (Smith 1989c). Residency programmes are criticised for not being diligent in filtering out incompetent candidates who make it through undergraduate programmes (Rhodes 1986).

Even if the basic and specialisation process produces doctors competent to enter the medical profession, it cannot assure that they will be competent in twenty, ten or even five years, given the rapid advance of medical knowledge and, therefore, the rapid obsolescence of knowledge gained in medical school. Keeping doctors up to date is the task of continuing education. But only in the FRG is continuing education mandatory (Bundesärztekammer 1988, s. 7), and even there the obligation is so vague as to be unenforceable. A Belgian general practitioner is entitled to charge higher insurance fees upon the completion of 200 hours of continuing education, but there is no obligation or inducement to continue beyond this point (Nys and Quaethoven 1984). England required GPs to participate in continuing education at one time as a condition of

receiving merit bonuses, but dropped the requirement in 1978 (though it may be reinstated under a GP contract currently being negotiated).

Opportunities for continuing education do exist throughout Europe and current continuing education programmes no doubt make good doctors better. In the absence of enforceable obligations to compel or financial incentives to encourage attendance, however, it is unlikely that inadequate doctors will pursue the opportunities continuing education offers them to make their practice acceptable.

In the final analysis it is impossible to judge the extent to which professional education and licensure assures the quality of medical care. Certainly there is no movement afoot to abolish the current approach or to replace it with something else. It is safe to say, however, that it is risky to rely on education and licensure as the sole guarantees of quality, particularly as the educational exper ence of professionals recedes further and further into the past as they age. We turn then to consider mechanisms that supplement professional education in assuring the quality of health care.

V. Policing the boundaries: professional discipline

Licensure decisions not only control entry into but also exit from the medical professions. Licensure can in theory be used not only to assure quality by limiting the grant of licences to qualified applicants, but also for ridding the profession of incompetent and unqualified practitioners through licence revocation. The idea that physician licensure bodies have a major role to play in assuring the ongoing competence of doctors has been much advocated in the United States in recent years (AARP 1987, Kusserow et al 1986).

Each of the countries here studied has a medical disciplinary board which has the power to sanction doctors in various ways, including by revocation (or recommendation of revocation) of medical licences. Historically, these processes have been the primary mechanism available for policing professional performance. This section will assess the contribution of licensure to medical quality assurance.

Belgium

All physicians in Belgium must be members of the Order of Physicians (Les Ordres des Médecins or de Orde der Geneesheren).[12] The Order is composed of a National Council and ten provincial councils. Each of the provinces has one provincial council except for Brabant (Brussels) which has two, one French and one Flemish. Half the provincial councils are Flemish and half French.[13] The National Council (which is divided into a Flemish and French speaking section) is headed by a judge from the Court of Cassation, and by a Flemish and French vice president, both doctors. Ten of its delegates represent the provincial councils and six are proposed by medical faculties and appointed by the King (Anrys 1971). Its primary responsibility is to formulate professional rules governing doctors, including the ethical code (Anrys 1971). The provincial councils are composed primarily of doctors elected from the membership, but also each includes one judge and a delegate from the National Council. The principle function of the provincial councils is to handle medical discipline (Anrys 1971).

The professional obligations of Belgian physicians are set out comprehensively in a royal decree and in the Deontological Code of the Order.[14] If a doctor violates these obligations, a complaint can be made to the relevant provincial council. Most of these complaints originate from patients, but they also come from sickness funds, hospitals, employers, the public prosecutor, or other doctors (AR 79 1967, art. 20, s. 1). Upon receipt, a complaint is sent to the doctor for a response. The complaint and response are then screened by the board of the provincial council. The board is composed of the provincial council's president, vice president and secretary, its national council representative, and its judicial member

(AR 79 1967, art. 20, s. 1). This board can decide that an investigation should be initiated or propose to the council that a complaint be rejected. The council alone can decide whether or not to reject a complaint. If the council or its board orders an investigation, it will be conducted by one or two medical members and the judicial member of the council. The investigation may involve interrogating the doctor or patients and reviewing relevant medical records. Where necessary, assistance in the investigation may be obtained from inspectors from the Ministry of Health or INAMI.

If the investigation substantiates the complaint, a hearing will be held before the provincial council. At the hearing the doctor will be present and may be represented by counsel. The complaining patient who in fact initiates a proceeding will not be informed of the hearing and may not be present, as the hearings are not public.[15] At the hearing the judicial member is responsible for assuring that proper procedures are followed and that the decision is made without bias. If the council decides that a sanction is appropriate, it may issue a warning, censure, or reprimand, suspend the doctor for up to two years, or revoke the doctor's licence (AR 79 1967, art. 16). The sanction of revocation must be voted by a two-thirds majority.

A doctor dissatisfied with the decision of the provincial council may appeal to the French or Flemish National Appeal Council (AR 79 1967, art. 21; Van Lil 1987). An appeal can also be brought by the judicial member of the provincial council or concurrently by the president and one vice president of the National Council (which is informed of all provincial decisions, AR 79 1967, art. 21). The appeal councils are composed of five members named by the provincial councils, five named by the King, a clerk and a representative of the National Council (Anrys 1971). They conduct a *de novo* review of the entire case in public (AR 79 1967, art. 25, s. 4). The appeal councils may not only affirm or reverse a decision of a provincial council, but by a two-thirds vote may also increase the penalty assessed by it (Van Lil 1987). The decision of the appeal council can be appealed to the Court of Cassation, but only on issues of law (AR 79 1967, art. 23). A final decision resulting in suspension or erasure is reported to the relevant provincial medical commission, INAMI, the Attorney General, and the Minister of Health.

Cases involving mental or physical disability are handled separately from disciplinary cases by provincial medical committees, which are composed of representatives of the medical and paramedical professions, and have responsibility for a variety of public health concerns (AR 78 1967, arts. 36,37; Anrys 1971). These bodies have the power to retake a physician's 'visa', or permission to practise (which is normally granted as a matter of course by the provincial ministry to a doctor who has qualified for licensure) until the doctor regains capacity to practise (AR 78 1967, art 37, s.1(2)(b)). They may also limit or condition the physician's right to

practise. The decisions of these bodies are not considered disciplinary sanctions, but can be appealed to a national committee of appeal and from there to the Council of State (AR 78 1967, art. 37, s. 4).

It is difficult to determine the extent to which the disciplinary actions of the Order affect quality of care. The Deontological Code imposes obligations on the physician generally to deliver high quality care himself and to improve the quality of care in the setting in which he works (Deontological Code 1975, ss. 34, 35, 100). For 1984 and 1985, the most recent years for which data are available, the most common ground for discipline was neglect of duties to patients (122 cases). This category is referenced to articles 6 and 113 of the Deontological Code, however, which address respectively the duty to render assistance in emergencies and abandonment, rather than issues of competence and quality. The next most numerous categories of disciplined offences include having too many offices (the number of offices a doctor may maintain being regulated by the Order); neglect of collegial duties; and disrepute in private life. None of the other reported disciplinary categories are explicitly related to quality of care or to competence, although several, such as causing drug addiction or misuse of therapeutic freedom, may be implicitly related to quality.

Recently the Ministry of Public Health (Ministere de la Sante Publique) has proposed legislation that would bring about a number of changes in the Order of Physicians (MSP 1989). Membership of the Order's councils at all level would be modified, adding a representative of INAMI to the provincial councils; reducing the terms of office and minimum experience and maximum age requirements for members of the councils to bring in younger members; adding delegates of the royal academies and senior civil servants to the National Council, and adding a magistrate from the labour courts to the provincial and appeal councils. Disciplinary procedures would be elaborated to separate prosecutorial and judicial functions and all hearings would be held in public, to comply with European Court of Human Rights concerns. All complaints would have to be heard, and complainants would be given the right of appeal. If these changes were to be adopted, they would go some distance toward making medical discipline in Belgium less a matter of internal self-regulation and bringing it more under external control. The proposed changes are being resisted by the medical profession, which believes that they would result in wasting much time and energy on invalid complaints. It was not clear at the time of writing this report whether they would be adopted.

The Federal Republic of Germany

Medical discipline in the Federal Republic of Germany is governed by the Ärztekammer or physician chambers (AKs), which are also responsible for specialist training, continuing education, and regulation of ancillary outpatient personnel (Anrys 1971; Arnold et al 1982). There are 12 AKs in

the FRG and Berlin, one in each of the lands and two in North Rhein-Westphalia (Stobrawa 1989).[16] A national Bundesärztekammer coordinates the work of the AKs, but has no disciplinary authority.

A general licensing law, the Bundesärzteordnung, exists at the federal level, but is administered by the states. Each state also has a professional code (Berufsordnung) enacted by the AK on the authority of the state laws with the consent of the relevant state ministry. These are modeled after a national Berufsordnung of the national medical association, which itself has no independent legal authority (Bundesärztekammer 1988).

The procedures of the AKs vary somewhat from state to state. Those of the AK of North Rhein, which are typical, are described here.[17] Proceedings against a doctor before the AK must be initiated by complaint. Complaints most commonly come from patients, although they could come from other sources, such as other doctors or the criminal courts. A copy of the complaint will normally be sent to the doctor for a response, which will be reviewed, with the complaint, by the president of the AK. The president may in the case of technical violations send a letter of admonition to the doctor. He may also advise a patient complainant to consider initiating a case for compensation in a civil court or before a Gutachterkommission (see Section IX). More serious cases (about 10 per cent of all complaints) will be reviewed by the executive committee of the AK.[18] This committee of 18 members meets once a month. The director of the AK presents reports on medical complaints, a lawyer for the AK presents complaints involving primarily legal issues. The AK proceeds to discuss the case in private session. It may hold hearings, but rarely does. The dispositions available to the committee at the close of its deliberations are to dismiss the complaint, admonish the doctor, proceed to prosecute the case before the professional court (Berufsgericht) of the state, or advise the health minister of the state (Regierungspräsident) to revoke the doctor's licence.

The professional court of the state is composed of a judge and two doctors. It holds a public hearing, in which the AK acts as the prosecutor. This court may warn or admonish the doctor, fine him up to 100,000 DM, or find him unworthy to practise his profession (HeilBerG NRh s. 49). Only the Minister of Health of the Land has the power to revoke a licence, and under federal law an otherwise qualified doctor can only lose his licence if he is found guilty of behaviour which demonstrates his unworthiness or unreliability to practise his profession or for mental or physical incapacity (BAO ss. 3,5). As a practical matter, this means that a doctor will lose his licence only if he is convicted of a crime or becomes disabled. The Minister of Health can revoke a physician's licence without a referral from the AK or professional court, and in North Rhein it is not uncommon for the Minister to do so on his own motion, most commonly for conviction of fraud against the sickness funds. This may not be typical of Germany as a whole, however.

There are no nationally available statistics on medical disciplinary matters, and therefore it is difficult to judge the extent to which discipline addresses quality of care issues. The Bundesberufsordnung devotes a good deal of space to traditional professional issues, such as advertising and collegiality, and ethical issues, such as abortion and sterilisation. It also includes obligations for doctors to pursue continuing education (s. 7); to keep patient records (s. 11); to carry malpractice insurance (s. 8); and (recently added) to participate in quality assurance activities (s. 7a). The director of the North Rhein AK estimated that about a quarter of the cases before his AK deal with quality of care issues (including alcohol and drug abuse) a quarter deal with advertising, and the other half address miscellaneous ethical and professional issues. In response to a questionnaire sent out by the author, one AK wrote that disciplinary proceedings involving quality of care issues were so rare that no statistics existed with respect to them. Another AK sent an annual report for 1988, which indicated that out of 37 disciplinary proceedings the previous year, 27 dealt with fraud against the insurance funds and the remaining ten with a variety of professional disciplinary matters generally not related to quality of care. Finally, a third AK indicated that disciplinary proceedings most frequently were concerned with general professional obligations, fee matters, and poor medical notes. In sum, although quality issues are addressed by the Berufsordnung, they do not seem to constitute a large proportion of the disciplinary activities of the AKs.

England

The medical profession in the United Kingdom, including England, is governed by the General Medical Council (GMC).[19] Although the GMC is fundamentally a mechanism for professional self-regulation, it varies somewhat from the medical chambers of Belgium and Germany. Only 50 of its 97 members are elected by the medical profession, with the remainder appointed by the royal colleges or universities or nominated by the Queen. It has long had some lay members and, currently, 11 members are non-physicians (Medical Act of 1983, sched. 1, pt. I; GMC 1988b) Historically the GMC has been most representative of elite and specialist medicine, and elected representatives of the profession have only had a majority of the GMC since 1978 (Rosenthal 1987; Smith 1989b; Walton 1988a). The GMC has come in for a good deal of criticism of late, and proposals for its reform are being mooted (see Brazier 1985; Cook 1987; Robinson 1988; Smith 1989a).

The authority of the GMC resides in its maintenance of the register of medical doctors in the United Kingdom. A person need not be registered to practise medicine in the UK, but only registered doctors are entitled to certain legal privileges, including the right to sue for collection of fees for medical services (Medical Act of 1983, s. 46(1)). Moreover, the NHS

may only employ registered doctors. The GMC can remove a doctor from the register (or suspend his registration for up to one year or make it conditional on compliance with specified requirements for up to three years) if the GMC finds that the doctor has been convicted of a criminal offence or is guilty of serious professional misconduct (Medical Act 1983, s. 36). 'Serious professional misconduct' is defined as conduct 'reasonably regarded as disgraceful or dishonorable by his professional brethren of good repute and competency ...' (GMC 1989b, p. 2). A doctor's registration can also be suspended for up to one year or be made conditional for up three years if his fitness to practise is seriously impaired by his mental or physical condition (Medical Act 1983, s. 37).

The disciplinary functions of the Council are exercised by its Preliminary Proceedings and Professional Conduct Committees. The Preliminary Proceedings Committee is composed of 11 members, including two lay members. The Professional Conduct Committee has 32 members, 11 of whom sit on any one case. A PCC panel will usually include two lay members. Impairment decisions are made by the GMC's health committee.

Cases are initiated by the GMC when it receives a report of a conviction by a criminal court or a complaint or information suggesting professional misconduct from a patient, the Department of Health (based on Medical Service Committee proceedings disciplining general practitioners) or from the National Health Service (regarding doctors employed in its hospitals) (GMC 1989a; Merrison 1985; GMC 1989a; Smith 1989d). The GMC obligates doctors to report serious professional misconduct when they are aware of it, but relatively few do (GMC 1989b).[20] Complaints are screened by the GMC's staff and, in the majority of cases referred to a member of the GMC appointed as 'preliminary screener'.

Where the complaint involves an NHS doctor, as most do, the GMC will often suggest that the complainant consider pursuing the NHS or FPC complaint mechanisms rather than proceeding in the first instance before the GMC (see Section VI for a description of these procedures.) The GMC argues that these referrals assure that complainants will not miss the short (eight week) time limit for using these procedures, that dual investigations are impractical, and that individuals who do not choose to pursue NHS procedures or are unsatisfied with the result they obtain there may proceed before the GMC. These referrals have been criticised, however, as sloughing off serious charges rather than dealing with them directly, adding substantial delay to the review of consumer concerns, and unnecessarily discouraging complainants who are often intimidated by the whole process to begin with (Robinson 1988; Smith 1989d).

In 1988, 66 of the 967 complaints received by the GMC were redirected to the NHS and 760 were dismissed (GMC 1989a). Eighty cases were dealt with informally by the preliminary screener in consultation with two members of the preliminary screening committee (GMC 1988a; Smith

1989e). Where appropriate, this involved a letter of advice. A hundred and forty-three cases, involving the remaining 127 doctors, were referred to the Preliminary Proceedings Committee.

Before a case can proceed on to the PPC a complainant must hire an attorney and draft a sworn declaration.[21] The doctor will be notified of the charges against him and invited to respond. The GMC has no independent investigative staff but may, if necessary, ask its solicitors to further investigate complaints.[22] The complaint and response are then considered by the Preliminary Proceedings Committee.

The cases received by the PPC in 1988 involved a nearly equal number of criminal cases and serious professional misconduct cases. The PPC meets in private, and can refer a case on to the Professional Conduct Committee (PCC) for hearing, send a warning letter or letter of advice to the doctor, initiate an investigation into mental or physical fitness to practise, or dispose of the case without further action (Smith 1989f). The PPC has statutory power to impose an emergency suspension following a hearing if necessary to protect the public, but rarely does so (Medical Act 1983, s. 42 (3),(4)). In 1988 the PPC dealt with 64 doctors through letters of advice, and referred 33 doctors on to the Professional Conduct Committee.

Hearings before the PCC are formal and quasi-judicial in nature (Bayliss 1987; Rosenthal 1987; Smith 1989f). The case against a doctor is presented by attorneys representing the GMC or the complainant. The doctor is represented by his own attorney. The Committee considers sequentially the facts proved, whether they constitute serious professional misconduct, and what sanction is appropriate, deliberating and announcing a decision on each issue before proceeding to the next. Proceedings are normally held in public and deliberation in private, but the entire proceeding may be conducted in private in sensitive cases. The committee is advised by a legal assessor, who may, for example, allow admission of evidence not admissable in court if he considers it necessary. Allegations must be 'strictly proved by the evidence' (GMC 1989b, p.5), essentially proved beyond a reasonable doubt.

Sanctions available to the PCC include erasure from the register, suspension for up to 12 months, conditional registration for up to three years, or postponement of consideration (effectively putting the doctor on probation, Medical Act 1983, s. 36; GMC 1989b). In 1988 the PCC heard 52 cases involving 40 doctors, resulting in six erasures, 11 suspensions, two conditional registrations, one adjournment, one referral to the health committee, and 19 disposals without effect on the doctors registration (including six adjudged guilty and admonished) (GMC 1989a). A doctor whose registration is affected by a sanction may appeal to the Privy Council or seek judicial review (Medical Act 1983, s. 40), but few do and even fewer do so successfully. A doctor whose registration is erased can apply for reinstatement after ten months (Medical Act 1983, s. 41).

Since 1980, cases involving mentally or physically ill doctors, including substance abusers, have been handled through different channels (Smith 1989g; Walton 1989). Where such cases come to the attention of the GMC, the preliminary screener can ask the impaired physician to submit to examinations by two independent consultants and to submit any other relevant medical evidence. If these examinations establish impairment, the physician may submit voluntarily to a supervised treatment programme. If he refuses to cooperate, the case may be referred to the PPC and from thence to the health committee. The health committee may impose a suspension or conditional registration on the doctor (Medical Act 1983, s. 37). From 1980 through 1988 about 400 impaired physicians have come under the supervision of the GMC, but all but 61 of these have been dealt with voluntarily without the intervention of the health committee (GMC 1989a).

It is difficult to judge the impact of the GMC on the quality of medical care in England. The GMC's Blue Book on Professional Conduct admonishes doctors to maintain 'a good standard of medical care' (GMC 1989b, p. 10) and in 1988, 26 of the 143 cases considered by the PPC and 14 of the 52 cases considered by the PCC involved disregard of patient responsibilities (GMC 1989a). Only five of these resulted in action affecting licensure, however. Moreover, because the GMC relies heavily on the NHS for screening patient complaints, and because the NHS hospital complaint screening mechanism rarely results in case referrals to the GMC, the GMC's review of physician incompetency is limited almost solely to GPs (24 of the 26 cases considered by the PPCs). Critics of the GMC claim that it places nearly insurmountable barriers in the way of policing medical competence (Robinson 1988)[23], and its leaders candidly admit that the 'serious professional misconduct' standard fails to address all but the most egregious quality problems (Walton 1988a; 1988b)

A committee commissioned by the GMC to address this problem has recently reported (GMC 1989c). Its report opposes altering the disciplinary standard of 'serious professional misconduct', although it also recognises that very serious errors in treatment may meet this standard (see *Doughty v. General Dental Council*). It rejects the suggestion of adding a lesser offence of 'unacceptable conduct', suggesting that such problems should be dealt with by the NHS. It recommends that further consideration be given to the establishment of procedures for dealing with incompetency within the jurisdiction of the GMC, but suggests that this be preceded by evaluation of medical audit procedures within the NHS and further discussion with professional and other groups.

Sweden

Sweden has opted for a form of professional regulation very different from the professional self-governance model adopted by the other nations in

this study. Since 1980, doctors in Sweden have been disciplined by the Hälso-och Sjukvårdens Ansvarsnämnd or Medical Responsibility Board (MRB), an independent authority that functions like an administrative court.[24] The MRB is composed of a chairman (who is a judge) and eight members: three representatives of health care unions; a representative of the county councils; and four public representatives (usually members of parliament) (HoSP 1980, s. 20). Of these, only one, the representative of the physician's union, is likely to be a doctor. The MRB has jurisdiction over everyone concerned with the care of patients in hospitals or in independent practice, not just over doctors. In fact, however, about 80-90 per cent of the cases that appear before the MRB involve doctors and most of the remaining cases involve nurses or dentists (Rosenthal 1987). The MRB is not primarily concerned with licensure actions, but rather with investigating complaints and reprimanding or warning health and medical personnel who have intentionally or negligently failed in a professional duty (HoSP 1980, s. 12). It thus functions more as a complaint board than like a licensure board.

The vast majority of complaints before the MRB originate from patients (56 per cent) or their representatives (29.7 per cent), with a much smaller number coming from the National Board of Health and Social Welfare (Socialstyrelsen)(14.3 per cent), the Parliamentary Ombudsman, or the Office of the Chancellor of Justice (Carlsson and Issacsson 1989). In some cases, patients initially approach the National Board, which may conduct its own inquiry before referring the case on to the MRB. County councils are required by law to report to the National Board any instance where a patient has suffered or risked suffering severe illness or injury because of treatment (SOSFS 1988, s. 16). The National Board will investigate these cases and report back to the county council. While the primary purpose of this procedure is to supervise corrective action to improve patient treatment, about one-fifth of the cases reported to the National Board are referred on to the MRB for disciplinary investigation.

Complaints received by the National Board are sent to the professional complained of, who responds in writing (HoSP 1980, s. 30). This response is then submitted to the complainant, who may comment on the response (HoSP 1980, s. 31). The complainant's comments are then returned to the professional, and this exchange of documents may continue until both parties have had their say. The MRB can also conduct its own investigation, but rarely does. The exchange of correspondence and relevant patient records are then reviewed by an appropriate specialist consultant of the MRB, who, together with one of the MRB's lawyers, prepares a record and report to be submitted to the MRB. Until 1989 the MRB had to consider all complaints within its jurisdiction filed within two years of the incident complained of (about 75 per cent of the total number of complaints received), but the law now allows the Chairman to reject frivolous complaints.

The Board meets in private each week for from two to four hours to consider about 20 cases. The report on each case is presented by the expert who prepared it. Most proceedings are conducted based on the written evidence, but the MRB can, and occasionally does, hold oral proceedings at which the parties may be present (HoSP 1980, ss. 38, 34). The MRB normally accepts the report of the investigating expert, though it is not uncommon for the report to be modified. In about 80 per cent of the cases concerning doctors no disciplinary action is taken, though the report may be critical of the doctor (Nygren 1985; Rosenthal 1987). In most of the remaining cases the doctor is either warned or admonished. Disciplinary action is much more likely in cases initiated by the National Board (62 per cent) than in cases initiated by patients or their relatives (8-9 per cent) (Carrlsson and Isacsson 1989).

The MRB can revoke a doctor's licence or limit his prescribing privileges only in cases initiated by the National Board of Health and Welfare. The National Board initiates delicensure cases based on the mandatory reports it receives from hospitals, criminal convictions of professionals, or egregious cases referred to the National Board by the MRB. Licences can only be revoked involuntarily if the professional 'has been grossly incompetent in the practice of his profession or has otherwise shown himself to be manifestly unsuitable to practise the same', or is physically or mentally incapacitated (HoSP 1980, s. 15). Licence revocation is rare and most commonly based on substance abuse.

Decisions of the MRB can be appealed by the disciplined professional, the complainant, or the National Board to an administrative court, and in fact often are. Sweden is the only country in this study that allows complainants to appeal a decision not to discipline a professional.

It is difficult to judge the impact that the MRB has on the quality of medical care in Sweden. It certainly seems more focused on patient care issues than the boards of the other countries studied. Rosenthal's analysis of a sample of MRB files found that virtually all of the complaints reviewed dealt with patient care, including about 40 per cent with therapeutic error, 25 per cent with diagnostic error, and 25 per cent with general poor treatment and behaviour of staff (Rosenthal 1987). The analysis of Carlsson and Issacson of 1019 complaints processed between 1980 and 1985 found that 52 per cent of the complaints concerned bad treatment, 36.7 per cent concerned professional-patient interaction problems (Carlsson and Isacsson 1989).

The opinions of the MRB are public. It also publishes and circulates widely both annual and monthly summaries of its decisions, which must have an educational effect. Further, about 4-5 per cent of Swedish doctors are complained of each year, so many doctors have had personal experience with the MRB (Rosenthal 1987). Several prominent Swedish doctors with whom I spoke, however, noted that the MRB disciplines only

a fraction of the doctors whom it investigates, and opined that it has little impact on the care provided by most doctors.

The impact of professional discipline on quality of care

This section began with the proposition that professional disciplinary proceedings might improve the overall quality of medical care by ridding the professions of incompetents. This hope seems on the whole chimerical in the countries under review. Estimates from the United States, where medical training and practice resemble in many respects that of the countries under review, project that as many as 5 per cent of doctors are incompetent (Derbyshire 1984). Yet, over the eight year period from 1973 to 1980, studied by Rosenthal, only one in 5553 doctors in Britain and one in 3180 doctors in Sweden had their licences revoked per year (Rosenthal 1987). While comparable statistics are not available from Germany and Belgium, there is no reason to believe they are radically different. When one considers that many of these actions were taken for reasons having little to do with quality, and that revoked doctors often can regain their licences relatively quickly, there is little ground for believing that licence revocation has a serious impact on the pool of incompetent practitioners.

There is slightly more reason for believing that disciplinary actions short of licence revocation may have some effect on the quality of care. Though licence revocation is the function of licensure boards that draws most public attention, a public warning or reprimand by an august official body, or even involvement in a disciplinary proceeding regardless of the result, is surely no small thing, and must have a deterrent effect both directly on the doctor affected by it and indirectly on those who become aware of it. Nonetheless, the total number of disciplinary actions is also quite small – one per 483 doctors in Britain and one per 49 doctors in Sweden in 1980 (Rosenthal 1987).[25] And, again, in most of the countries under review discipline is usually not directly related to quality issues.

Moreover, an examination of the structures, procedures, and aspirations of disciplinary boards gives one little reason for hoping that they will have a significant impact on the quality of medical care. In all of the countries under review but Sweden the vast majority of members of medical licensure boards are physicians. Indeed, in Germany and in the provincial councils of Belgium all voting members are doctors. Too much has probably been made of this fact. As Rosenthal has pointed out, the consumer-dominated Swedish Medical Responsibility Board, if anything, disciplines less severely than the medically-dominated General Medical Council (Rosenthal 1987). Ultimately lay members of medical boards must rely on the advice of medical professionals for identifying lapses in the technical aspects of medical care and lay members may be easily intimidated, persuaded or socialised into taking on the views and values of

medical board members or experts. Nonetheless, assertive lay members can play an important role in advocating protection of the public in situations where some medical members might be too quick to understand and forgive serious lapses in care.[26]

Other factors, however, probably play a greater role in restricting the effectiveness of the disciplinary bodies under review. First, and most importantly, most licensure boards are not primarily concerned with the competence of practitioners or with the quality of the care they deliver. Professional boards exist historically to police the boundaries of the professions: to keep non-members from poaching the privileges of members and to make sure that members behave themselves so as not to bring the profession into public disrepute. Though the boards in the countries here under review have come a long way towards seeing their role as protecting the public from incompetent professionals as well as from advertising, in all countries except Sweden the bulk of their work is still focused on 'professional' issues as traditionally defined. Indeed, the more candid of those interviewed admitted that their role in policing competence did not go beyond dealing with the most egregious situations.

Second, the problem identification methods of the boards greatly limits their effectiveness. All of them depend primarily on patient complaints for initiating actions. More will be said about the usefulness of consumer complaints for identifying quality problems in the next section. Suffice it to say here that while consumer complaints may help to identify some dramatically bad outcomes of care (which may or may not have been caused by quality lapses) and may identify some professionals wholly deficient in interpersonal skills, they will in many cases fail to identify practitioners whose technical skills are substandard. None of the bodies rely on audit or professional reporting requirements, which might be much more effective in identifying poor quality practitioners.[27]

Third, the fact-finding techniques of the disciplinary boards under consideration here are very weak. None of the bodies routinely investigates complaints beyond obtaining the doctor's response and perhaps reviewing relevant records. None seemed to have investigative staff trained in police techniques, and those with access to outside investigators seldom use them. None seek to determine if a lapse of care is unique or part of a larger pattern of poor care by interviewing other patients of a doctor or by going to his office to inspect other records. Hearings seldom go beyond the testimony of the patient and the doctor, perhaps supplemented by a review of the records or expert commentary on the doctor's performance. If there is a factual dispute and the testimony of the patient and doctor are equally credible, the doctor must usually win, since the burden of proof for discipline will not be carried. Patient complaints of problematic interactions with professionals are particularly likely to end in a conflict between the patient's and the professional's version of events, with no independent verification of either version possible, even from the medical records.

Fourth, most of the boards lack sanctions appropriate for addressing quality issues. Ideally, a range of sanctions including requiring additional education, re-examination, supervision by another doctor, limitation of practice to certain types of practice or practice settings, withdrawal of prescribing privileges, or monitoring by the licensure board, could address specific problems (AARP 1987; Federation of State Medical Boards 1986). Only England, however, has the power generally to impose conditions on licensure, and this power was only used twice in 1988 (GMC 1989a). Revocation is such a serious sanction as to be warranted only in the most egregious cases. Sanctions less stringent than revocation but more directive than a general admonishment are needed.

This is not to say that licensure boards have no role in quality assurance. First, they do have some deterrent and educative effect, as has already been mentioned. Much more could be achieved in this area, however, by a board dedicated to education. The regular publication of decisions by the Medical Responsibility Board in Sweden has provoked discussion as to the appropriate treatment in various kinds of cases (Hellner 1985). Other boards could be much more public about their activities and decisions.

Moreover, by maintaining professional standards the boards also contribute to the maintenance of quality standards. An anecdote related by the Registrar of the GMC concerning a junior doctor illustrates this relationship. After an exhausting 22-hour day the junior doctor had just lapsed into a deep sleep when she was awakened and told that an attempted suicide victim had just been brought into the emergency room, still alive but completely covered with severe burns. The junior doctor, whose own competence was still limited, knew objectively that in this particular case there was nothing that even the most competent doctor could do to save the victim's life, but that professional obligations, as enforced by the GMC, necessitated attending the patient. Such a sense of professionalism, still quite strong in the countries visited, inspires a doctor to practise high quality medicine. To the extent that medical boards encourage and maintain such professional values, therefore, they do make a contribution to quality assurance. Having said this, however, it must also be said that disciplinary boards fall far short of the complete task of quality assurance.

VI. Channelling consumer dissatisfaction: complaint investigation procedures

If the quality of a product is poor, consumer dissatisfaction with the product should become evident. This dissatisfaction will reveal itself in complaints if complaint mechanisms are available. Curiously, of the four countries under examination only England and Sweden, the two countries with public provision of medical care, have public systems for receiving and investigating complaints regarding health care. Presumably this is because of the greater need for public accountability where a medical care system is publicly owned. It may also be attributable, in part, to the fact that publicly managed health care systems are better able to compel cooperation with complaint investigations and to take disciplinary or corrective action when investigations reveal that such action is necessary.

England

The NHS complaint system bears a remarkable resemblance to the mazes sometimes found in the gardens of English country houses.[28] Separate formal processes exist for the general practitioner and the hospital services, and within the hospital services, for clinical and administrative complaints. The Health Services Commissioner, an independent ombudsman, has a limited remit for examining complaints regarding maladministration or the failure of a health authority to provide a service or to provide it properly. Community health councils are responsible for assisting patients, and to that end sometimes conduct their own complaint inquiries. Informal processes exist on both the GP and hospital side for addressing patient dissatisfaction. Finally, a variety of disciplinary procedures are available for dealing with confirmed problems involving staff of the NHS.

1. Complaints involving general practice

On the general practice side a procedure is available for addressing patient complaints, the roots of which go back well beyond the founding of the National Health Service (Klein 1973). This procedure does not exist as such to investigate and resolve patient complaints, but rather to assure that GPs comply with their contract with the NHS. Thus, for example, doctors can be sanctioned for incompetence, refusing to visit a patient at home where warranted, or failing to refer a patient where necessary – all matters addressed by the GP contract (NHS Regulations, schedule 1, part 1, ss. 3 and 13) – but cannot be sanctioned for their own rudeness or the rudeness of their staff, as the contract does not require politeness.

A patient dissatisfied with the services provided by a GP must complain in writing to the administrator of the local family practitioner committee (FPC) within eight weeks of the event which gave rise to the complaint.[29]

The administrator reviews the complaint to determine if it involves an alleged contravention of the GP's contract, and thus falls within the jurisdiction of the committee. If the complaint seems to address a contractual issue, the practitioner is asked to comment, and the practitioner's comments are shared with the complainant. The matter is often resolved informally at this point. Indeed, many FPCs have a separate informal procedure through which the complainant and practitioner can meet with a conciliator for expedited resolution of problems. If the matter involves a contractual issue and cannot be resolved, it is referred to the FPC's medical services committee (MSC), which holds a hearing.

The MSC is composed of three lay and three professional members, plus a lay chairman. At the MSC hearing both the complainant and practitioner present their cases, including any witnesses. They may bring advisers to the hearing, but may not use the services of paid counsellors for presenting their cases. The MSC reports its findings of facts and conclusions to the full FPC, which may choose to alter the MSC's recommendations if it gives its reasons for doing so. The FPC may decide to reject the complaint, limit the size of the practitioner's list, warn the practitioner, deduct from the GP's remuneration expenses reasonably due to the complainant, withhold remuneration or, in very rare and egregious cases, recommend to a NHS Tribunal that the practitioner's contract be terminated. In severe or multiple cases, the FPC may also communicate its results to the relevant licensing body, such as the GMC. Dissatisfied practitioners or complainants may appeal to the Secretary of State, who may convene a more formal oral evidentiary hearing, heard by a panel of two doctors and a lawyer. Finally, if a fine has been imposed the practitioner may appeal the amount of the fine without the complainant knowing of the appeal.

The FPC process just described has been criticised by those who allege that the very short statute of limitations cuts out many complaints, the formality of the process intimidates complainants, and the procedures favour practitioners (Cook 1987; Robinson 1988; Sinclair 1987). Modest proposals made by the government to improve the procedure were made in 1986 but have not yet been implemented (DHSS 1986).

In 1981 there were 705 FPC medical service committee investigations. In 584, no breach of contract was found. Thirty-two investigations resulted in withholdings (Rosenthal 1987). Klein's research indicates, however, that complaints processed through the FPC machinery involve only a tiny fraction of expressions of dissatisfaction. For every formal complaint, 100 patients 'grumble' or express dissatisfaction in some other way, and 400 change doctors while remaining at the same address, presumably often because of dissatisfaction with their doctor (Klein 1973).

Complaints most commonly involve failure of the doctor to examine the patient properly, refusal of the doctor to visit, difficulty in getting access to a doctor, lack of treatment, and non-referral to hospital (Allsop 1988;

Klein 1973). They normally concern the treatment of very young or very old persons or problems related to pregnancy, and often involve a death (Allsop 1988). Breaches are much more likely to be found by the MSC where there are allegations of a moral or organisational failure than when a technical judgment is questioned (Allsop 1988; Klein 1973). As MSC hearings are held in private, and neither the FPCs or the Department of Health make any effort to publicise their results, the process serves only a minimal educative or deterrent function for the conduct that it addresses.

2. Hospital complaints

Separate appeal procedures exist for hospital complaints involving clinical and non-clinical matters. Most minor criticisms of either type are dealt with informally at the ward level by nursing staff. A patient or patient's representative with a serious complaint addressing non-clinical aspects of hospital care must within three months of the complained of incident put the complaint in writing and address it to the designated complaint officer in the hospital (DHSS Health Circular 88(37)). This officer will investigate the complaint, seeking a response from the staff complained of and perhaps additional information from the complainant. Cases involving complaints of serious untoward incidents involving harm to a patient, conduct subject to disciplinary action, physical abuse of patients, or criminal conduct are to be referred immediately to district or regional management for appropriate action, including where necessary suspension of staff. When the investigating officer completes his work, he will write a response letter to the complainant, sending copies to appropriate staff. A complainant dissatisfied with such a report may proceed to contact the Health Services Commissioner.

Complaints involving clinical judgment may be made orally or in writing, but must in the first instance be directed to the consultant responsible for the patient. The consultant should attempt to resolve the complaint expeditiously by discussing it with the patient and with any other medical staff involved.[30] This should result in a response to the patient from the district administrator, drafted with the assistance of the relevant consultant. A patient who is dissatisfied with this response may complain in writing to the regional medical officer (RMO), who will discuss the matter with the consultant and the complainant. If the result of this process does not satisfy the complainant, the RMO can, at his discretion, seek a 'second opinion' from two outside consultants, who will hold a consultation with the patient and make recommendations to the RMO. The district health authority will then advise the complainant of the results of this process. Before the complainant may proceed to this third step, the RMO must establish that the complaint is not likely to result in legal action. The RMO usually does this by securing a representation from the complainant that he is not planning to sue,

although these representations are widely regarded as unenforceable (Anon 1988b; Capstick 1985).[31]

Criticisms of the hospital complaints system focus most often on the fact that it does not offer a truly independent review of hospital actions (Robinson 1988; Rosenthal 1987). The 'second opinion' process is only available at the discretion of the RMO, and the opinions of the outside consultants are only made available to the patient after having been filtered through the RMO and district authority. Complainants not infrequently experience delay and obstruction, and problems with the hospital complaints system forms an important part of the work of the Health Services Commissioner.[32]

The complaints system is in fact used. In 1986, health authorities received 28,872 complaints involving hospital services (10,864 involving clinical judgment) approximately 3.9 per every 1000 inpatient or day cases (DH 1989e). Few of these cases, however, get beyond the district level. In 1986, nine cases resulted in an independent inquiry, and 71 were referred to two independent consultants (DHSS 1989e). Clinical complaints do address quality issues, at least indirectly. The most common grounds for clinical complaints are failure or delay of diagnosis and inadequate or inappropriate treatment (DHSS 1983b). As complaint investigations often seem to be concerned primarily with defending the health authority and its staff from charges of incompetence, it is not clear that complaints often result in improved performance.

3. The Health Service Commissioner.

The most publicly visible investigator of health services complaints is the Health Service Commissioner, the national ombudsman for health care. Considering this notoriety, it is remarkable how limited the jurisdiction of this office actually is. The HSC may only investigate alleged failures of service, failures to provide a service, and maladministration by health authorities (NHS Act 1977, s. 115). He may not inquire into matters of clinical judgment, actions of general practitioners under contract with FPCs, for which grievances there is another legal remedy, formal actions of FPCs, personnel matters, properly taken discretionary actions, complaints made more than one year after the actions complained of, or complaints not first submitted to the health authority through proper channels (NHS Act 1977, ss. 110, 113, 115, 116).

Complaints to the HSC must be made in writing by aggrieved persons or, where necessary, their representative (NHS Act 1977, ss. 111, 114). If the HSC determines that the complaint falls within its jurisdiction, it will send the complaint to the person or entity complained of and request a response, including all relevant papers. One of the HSC's investigators will then proceed to investigate the complaint. The HSC has the power to hold oral evidentiary hearings, but does so only very rarely. The investigation results in the issuance of a report by the HSC to the

complainant and complained-of authority. A draft of the report is shared with the authority complained of and principal witnesses, but not with the complainant. When the complaint is upheld, the report will usually recommend remedial action. This may involve an apology, changes in procedures, or ex gratia payments (for example, for lost property). The HSC has no enforcement powers, but when its confidential recommendations are ignored, it can criticise the recalcitrant authority publicly before the Select Committee of the Parliamentary Commissioner for Administration, a step which usually brings action. There is no appeal from the decisions of the HSC, though his actions are probably subject to High Court review.

In the 1987–88 annual reporting period the HSC received 794 complaints (668 from England). During that year 725 cases were rejected, discontinued or closed (reflecting the very limited jurisdiction of the HSC) and 133 reports issued. Of the 525 grievances considered in the 133 reports, 61.14 per cent were found to be justified (HSC 1988). Each year the HSC publishes an annual report and two 'epitomes', anonymised summaries of about two dozen of its cases. These reports identify particular problem areas. For example, the 1987–88 annual report considered supervision of psychiatric patients, community home and mental handicap care, discharge arrangements, and handling of clinical complaints. This contrasts sharply with the secrecy which surrounds most of the other complaint procedures, and could serve an important educative role.

4. NHS disciplinary procedures

Successful patient complaints involving serious misconduct or incompetence can result in disciplinary procedures. So can allegations by hospital staff or management challenging the conduct or competence of other professionals. Disciplinary procedures arise in the context of employer-employee relationships, and thus involve all of the complexities of employment law. In the National Health Service, these complexities become even more labyrinthine, with separate procedures for allegations involving personal conduct, professional competence, impairment, legal incompetence and other causes (See Bunbury and McGregor 1988). These procedures are quite lengthy, sometimes taking years to complete. An authority may, however, take immediate action to suspend a professional from duty – with pay – in cases of a very serious nature (HM(61)112, s. 2). According to one recent report, 60 doctors are currently suspended from the NHS while disciplinary procedures proceed (Brahams 1988).

The most controversial recent example of the use of disciplinary proceedings to address competence issues was the Wendy Savage case (BMJ 1986). In this case, charges of incompetence were brought against a woman gynaecologist by her colleagues. After well-publicised proceedings,

the charges were ultimately rejected. It was widely believed that the real problems in the case were ideological and personality incompatibilities. The bad taste left in the mouth of the NHS by the entire proceeding, and the controversy it provoked, however, might well deter competence-based disciplinary actions in the future.

Effective and expeditious disciplinary procedures are necessary if complaint investigations are to play a significant role in quality assurance. Without them the only possible response to a legitimate complaint is an exhortation to do better. The complexity and delay inherent in NHS procedures give little grounds for confidence in their efficaciousness. Summary suspension may partially make up for this, but it is a terribly inefficient remedy (as doctors continue at full pay throughout the suspension) and unfair to the doctor whose name is eventually cleared.

Sweden

Compared with the Byzantine complexity of the British system, the Swedish complaints process is quite straightforward. Complaint mechanisms exist at both the county and national level. Under Swedish law, each county must have one or more complaint, or 'confidence' boards to 'promote contacts between patients and health and medical staff and also to give patients the assistance which circumstances require.'[33] The Stockholm board accepts both oral and written, and even anonymous, complaints. It does not require complaints to be made within a limited time period. When complaints are received, the staff of the board usually contact the chief of the hospital at which the complained of incident occurred both to obtain additional information and to make certain that the hospital is aware of the problem. Where staff investigation reveals a serious problem, it is referred to the board itself for consideration at a monthly meeting. Half the board members are politically elected members of the county council and none are doctors. The board has no disciplinary powers, and can only investigate and discuss the problem and suggest solutions. It refers serious complaints involving medical personnel to the MRB. During 1982 the Stockholm board received 412 complaints, with the single largest category of complaints involving poor personal treatment by nurses (Rosenthal 1987).

Serious complaints involving medical personnel are handled by the Medical Responsibility Board. The MRB was discussed above as a disciplinary body, but it should be noted that its most important function is not to address licensure matters, which it does only rarely, but rather to investigate complaints regarding the competence and behaviour of medical professionals. It thus performs an analogous function to the FPC and clinical judgment complaint procedures in England. As in England, if a serious complaint against a doctor is upheld, his employing hospital may take disciplinary action. As in England, however, it is very difficult to do so successfully.

COMPLAINT INVESTIGATION PROCEDURES

Complaints and quality

What role do complaint systems play in assuring quality? First, they can potentially identify specific instances where a patient suffered a bad outcome, perhaps because an individual or institution failed to provide care of acceptable quality. Second, clusters of complaints may point to the existence of a general weakness in a system or lack of competence in a particular professional. Third, at the highest level of abstraction, the general level of complaints may indicate a general dissatisfaction with medical care, in turn pointing to large-scale systemic quality problems. At each level, investigation of complaints may indicate action that can be taken to correct problems and thus improve quality: modification of procedures, reallocation of resources, discharge or transfer of personnel.

It is not clear, however, that the complaint systems of England or Sweden serve these goals very effectively. First, patients are limited in their ability to recognise poor quality care. Complaints thus tend to focus on particular kinds of problems – organisational failures, attitudinal problems, and technical failures that led to dramatic results such as death – and to miss more subtle failures that may indicate more fundamental quality problems.

Second, at least in England, only a very small percentage of patients who are dissatisfied with their care actually take the trouble to pursue formal procedures, and those who do are often disappointed with the system's response. A recent study of four health authorities in the UK, for example, found that two-fifths of those interviewed had wanted to complain at some point, but only 6 per cent had actually done so (Prescott-Clark et al 1988). Of these, most informally approached nursing staff, only 4 per cent went to the health authority and 1 per cent to the GMC (Prescott-Clark et al 1988). Over half were not satisfied with the resolution of their complaint. Those who wanted to complain but did not do so gave as reasons lack of knowledge as to how to complain, a belief that complaining was pointless, not wanting to make trouble, or fear of retaliation. The formidability and complexity of complaint procedures no doubt discourages many potentially meritorious complaints. The Balkanisation of jurisdiction that typifies the English system, combined with relatively short limitations periods, undoubtedly deflects many others. The delay inherent in the procedures (which can take years), and the fact that the personnel complained of are often involved throughout the process, impedes efficient and fair resolution. The complexity of the English disciplinary procedures further discourages prompt and effective action where problems involving personnel are discovered through complaints. Finally, the secrecy that enshrouds the entire process (except for the work of the HSC) ensures that little is learned from complaints that succeed.

The Swedish system is much simpler, and should be free from many of

these limitations. But even in Sweden some experts interviewed expressed scepticism as to the usefulness of the process for improving the quality of care, as opposed to mollifying the dissatisfactions of patients. In particular, the confidence boards only deal with administrative matters and do not question physician judgment.

Complaint processes can be useful for identifying some quality deficiencies. They are of much less use for identifying other problems, however, particularly lapses in technical medical quality. Even where complaints are relevant, complaint processes must ultimately be capable of resulting in disciplinary actions against individuals or in organisational changes in institutions if they are to play a role in quality assurance. Though such interventions can result from complaints in both England and Sweden, it is not clear that they are frequent enough to have a significant impact on medical care quality.

VII. Paying the piper and calling the tune: insurance review of medical care

The thesis that launched this article, again, was that European countries with decades of experience of near universal provision of medical care would have developed mechanisms similar to the PROs of the United States for monitoring the quality of medical care. While none of the four countries here under review have developed cognates of the PROs, the insurance systems of two of them, Belgium and the FRG, have developed mechanisms for monitoring the utilisation of insurance funded services. Neither country's programme directly monitors the quality of medical care, but the programmes of both do tangentially affect health care quality, and could be adapted to play a more direct role.

The Federal Republic of Germany

The sickness funds of Germany have an obvious interest in deterring fraudulent claims and over-utilisation of insurance funded services.[34] Because of the method used for payment for ambulatory physician services – division of a fixed total budget among participating physicians based on the volume and value of services each claims to have provided – doctors as a group, represented by the Kassenärztlichen Vereinigungen (Organisation of Insurance Doctors or KV) also have an interest in no one doctor claiming an excessive share of the pie. Since the early 1930s, therefore the FRG has had a system of economic monitoring to review claims by physicians for insurance payment (Döhler 1988; Stone 1980).

Under this system the KVs create each quarter a profile for each participating physician, comparing the average number of claims per patient for each physician with averages of physicians of the same region and same specialty for the same type of services rendered to patients of the same insurance category and sickness fund. Total fees are also compared. Where excessive claims (usually 40 per cent above the mean) are detected in a particular case, the case is examined further to identify special circumstances that might justify higher claims. If these are not found, the doctor is asked to explain the discrepancy. If this statement is not adequate, the doctor is asked to appear before a monitoring committee, composed of representatives of the KV and sickness funds. If the committee determines that the doctor has charged for excessive services, it may warn the doctor, cut back his reimbursement, demand that the doctor pay back the cost of excess drug prescriptions or, in egregious cases of repeated violation, revoke the doctor's right to practise as an insurance doctor. The decision of the monitoring committee may be appealed to an appeal committee and ultimately to court.

Under the 1988 health reform law the committees will also review each doctor's performance relative to pre-established prescribing budgets (SGB

V, ss. 84, 106(2)). They will also comprehensively review each quarter the performance of 2 per cent of the doctors under their jurisdiction with respect to the total costs generated by the doctor through prescriptions, referrals to specialists, hospital admissions, and disability certifications (SGB V, s. 106). Presumably the same sanctions and appeal rights will be available for doctors whose practices fail these measures.

Physician practice in Germany has also been subject to review for over half a century by the 'Vertrauenärztlicher Dienst' or control doctors, whose primary function has been to review disability certification to deter malingering (Stone 1980). Under the 1988 health reform law the control doctor service is expanded to a broader 'Medizinischer Dienst' (MD), directly under the control of the sickness funds (SGB V, s. 275).[35] The remit of this body is to monitor more generally the necessity of medical care, including, specifically, rehabilitation services, home health care, orthodontics, and ambulatory dialysis, in addition to the traditional control doctor function of reviewing disability certification. Significantly, the MD also is authorised to advise the sickness funds in medical matters, including, specifically, 'questions of quality assurance'. (SGB V, s. 275).

Belgium

Belgium also has both a statistical profile review programme and a programme of control doctors, though its control doctors focus on correctness of physician billing.[36] Both programmes are operated by INAMI, the national sickness fund institute. The profiling committee (which includes representatives from the sickness funds, universities, medical associations, INAMI and the Control Service) examines computer profiles compiled annually on all insurance doctors, considering both billing for services and prescribing patterns. Where a doctor's profile deviates so far from the mean as to indicate fraud, and the deviation is not explained by demographic or medical considerations, the committee can request an explanation. If the explanation is not satisfactory, the committee can refer the case to the Order of Physicians, the criminal prosecutor, or to INAMI's Medical Control Service. The Ministry of Health and Social Affairs has recently proposed decentralising activity profiling to give colleagues in the same area more responsiblity for the practices of their peers.

The inspector's of INAMI's Medical Control Service have the status of law enforcement officers. They can demand access to medical records and can issue citations directly where they detect improper billing. Their function is to monitor billing, to assure that doctors' bills comply with the nomenclature of the insurance system. If, for example, a doctor bills for 30 services for one day that under the nomenclature are supposed to take 30 minutes each; or bills for an x-ray procedure that is supposed to require three films, but can only produce one; or bills for the use of equipment

that is not in working order, Medical Control can issue a citation disallowing payment for the service. Medical Control investigations are initiated either based on complaints from patients, the insurance funds, INAMI, or the profiling committee, or by the Control Service itself.

Medical Control doctors refer serious cases, and cases where the doctor contests the citation, to INAMI's Medical Control Committee. This committee reviews referred cases, and sends serious cases on to a chamber composed of three doctors from the funds, three from the medical associations, and a non-voting magistrate. The control committee can fine a doctor or bar him from reimbursement for a period of from five days to one year. A sanctioned doctor can appeal the sanction decision to an appeal committee within INAMI, and beyond that to the Court of Cassation.

The insurance funds also employ their own medical advisers who review disability claims. These advisers can also be used to investigate patient complaints or suspected fraud. Where minor problems are identified by these investigations, a fund may settle with the doctor for repayment rather than refer the case into the more draconian Medical Control system.

Insurance review and quality assurance

The role that insurance review presently plays in medical care quality assurance is quite limited. In Belgium, the law prohibits the insurance companies from interfering in the practice of medicine – that is, in 'diagnosis, treatment, or the preparation of medicaments'. (AR 78 (1967), art. 11). Abuses of this professional freedom by doctors may only be punished by the Order of Physicians (Farber 1988). Although the law in Germany is not so explicit, the insurance companies there also have little interest in policing the quality of medical care.

Moreover, existing review systems are quite limited in their capacity to affect medical care. Only a small fraction of physicians claims are denied through the monitoring system. In Germany it effects about 10 per cent of fund doctors, resulting in a cutback in 5 per cent of all cases, but actual cutbacks are focused on a small number of doctors (Döhler 1988). Moreover, the primary sanction relied on by both systems, denial of payment, has little deterrent effect, since the only penalty for submitting inappropriate claims is that some may be disallowed (Stone 1980). Commentators in both countries reported that physicians employed as control doctors often tend to be doctors with limited qualifications who could not find employment elsewhere as doctors and who thus have only a limited ability to challenge the quality of care provided by other physicians.

Nonetheless, insurance monitoring probably has positive effects on quality. Excessive provision of medical care, the principle target of both

systems, surely has harmful effects. Limiting unnecessary care contributes, therefore, to quality assurance. To the extent that some aspects of the Belgian insurance nomenclature address standards of care (for example, time to be spent in therapy, equipment to be used for diagnostic tests), review for conformity to the nomenclature is a basic form of quality review. Control doctors who review disability certifications occasionally suggest alternative diagnoses or treatments, thus contributing to the care of incapacitated persons.

Perhaps most significant, however, is not the current function of economic monitoring in the FRG and in Belgium, but its potential function. Both countries have developed extensive systems for computer profiling of medical providers and for investigation of particular problems in the provision of medical care. If, at some point in the future, these countries became interested in data- and investigation-based quality monitoring programmes, similar to the American PROs, they would merely have to adapt monitoring systems already in place. There is little current interest, however, in moving in this direction.[37]

VIII. The institutional focus: inspections

The primary regulatory strategy relied on in the United States for monitoring the quality of care in medical institutions is the inspection. This is particularly true with respect to nursing homes, where the federal Nursing Home Reform Act of 1987 (Pub L No 100–203, ss. 4201–4218) relies heavily on a complex inspection process, but it is also true with respect to hospitals, which the Joint Commission for the Accreditation of Healthcare Organizations inspects triennially. There is much less emphasis on inspections in the countries here studied. Where inspection programmes exist, they tend to focus more on planning than on quality concerns. In each of the countries under consideration, most of the hospitals are operated by the government or (in Belgium and the FRG) by voluntary organisations. There is little interest in inspecting publicly owned hospitals, although, for example, the National Board of Health of Sweden retains the authority to inspect county council owned facilities and uses it in extreme circumstances, and the Health Advisory Service in Britain regularly reviews publicly provided services for the elderly (Day et al 1988; Horrocks 1986). The Audit Commission of England and Wales is also beginning to audit the NHS, and will look at quality issues as part of its concern with value for money issues (Audit Commission 1989).

Inspections are most common with respect to nursing homes, which are more likely to be privately owned and operated. In Sweden private nursing homes are inspected by the county councils, which can recommend that the National Board of Health and Welfare revoke the licence of seriously deficient nursing homes. In Germany private homes are inspected by local authorities, which finance rest home services through social service programmes (Ross 1984). In Belgium, hospitals and nursing homes are inspected by the National Board of Health, but these inspections have until now tended to focus on structural characteristics.

The inspection system that most nearly resembles systems used in the United States is that created by the Registered Homes Act of 1984 in Britain. The Registered Homes Act covers private nursing homes and residential care homes (Registered Homes Act 1984, see generally Davis 1987; Day and Klein 1987a; and Stanniland 1987).[38] The former are defined as facilities that provide nursing care to the sick, injured or infirm and the latter as facilities that provide personal care, room and board (Registered Homes Act 1987, ss. 1 and 21). Residential homes are registered and inspected by local authorities and nursing homes by district health authorities. Private provision in both kinds of facilities has grown rapidly in the last decade – there are currently 64,000 nursing home beds and 124,000 residential care places, equivalent to a quarter of all NHS acute care beds (Anon 1988a). A significant number of homes are 'dual registered' as both nursing and residential homes. Nursing homes are the focus of the discussion here, as they are more 'medical' institutions.

Private nursing homes must establish that they meet statutory and regulatory requirements before they can be registered. The most important of the statutory requirements are that the applicant is a 'fit' person, the home is a 'fit' home, and that the home is managed by a registered medical practitioner or qualified nurse (Registered Homes Act 1984, s. 25(1)(a), (b), (f)). The Registered Homes Act is implemented by regulations, which impose requirements only slightly more specific than those found in the Act. Section 12 of the regulations, for example, requires that facilities 'provide adequate professional, technical, ancillary and other staff' and 'provide for each patient in the home adequate accommodation and space, including, where appropriate, day-room facilities.' Specification of what these requirements mean, however, is largely left to the nearly 200 district health authorities that enforce the Act. Guidelines developed by these authorities are commonly based on the model guidelines developed by the National Association of Health Authorities (NAHA 1985b, NAHA 1988), but increasingly also reflect the concerns of individual health authorities. These guidelines vary significantly, but some represent innovative attempts to explain the intangibilities of quality. Although the initial NAHA guidelines tended to focus on structural considerations (such as the physical plant, staffing, equipment, and documentation) some of the recent district authority guidelines focus more directly on patient care and to some extent rely on process or outcome measurements. A 1988 supplement to the NAHA guidelines also puts more emphasis on quality of life issues, including protection of patient dignity and provision of social services (NAHA 1988). Efforts are now being made to disseminate the more innovative guidelines more widely to encourage their emulation.

Health authorities are required to inspect facilities biennially, but most health authorities visit more often, particularly where they identify substandard facilities. Inspectors tend to see themselves as educators or consultants, rather than as policemen (Day and Klein 1987b), but can take decisive action where conditions warrant it. The highly localised character of enforcement may keep inspectors in closer touch with the community environment of the facilities they regulate, but also contributes to wide variations in both the quality of the inspection process and in what is demanded of regulated homes (NCVO 1988; Social Service Inspectorate 1988). This problem is being addressed by increased training for inspectors carried on at a national level, but calls are also emerging for a national inspectorate or accreditation programme (Day and Klein 1987a; Davis 1987; Vellenoweth 1988) or for transferring the inspection function to the local authorities, currently responsible for inspecting residential homes (Griffiths 1988).

Where inspections reveal serious noncompliance with registration requirements or the manager of the home is convicted of serious offences against the Act, registration may be cancelled (Registered Homes Act

1984, s. 28). Where a serious risk to the life, health, or well-being of patients is established, a justice of the peace may enter an order cancelling the registration of a home or varying or imposing conditions on the home (Registered Homes Act 1984, s. 30). Appeals of cancellation decisions are made to special Registered Homes Act tribunals consisting of a legally qualified chairman and two members with social work, medicine, nursing or midwifery experience.

Ultimately, standards for registered nursing homes are set by these tribunals. Recognising that no national guidelines are in place with respect to nursing homes, the tribunals treat local guidelines as advisory only, and often visit homes themselves to arrive at their own assessments. Of the 30 appeals decided between the autumns of 1987 and 1988 (including both residential and nursing homes), the decision of the inspecting authority was reversed in 14, nearly half. Quotes from these decisions reflect their tone: '. . . an Authority should not impose requirements which are too far out of line with those of most other Authorities in the Country. If an Authority does go down this road it should be prepared to justify its requirements with convincing evidence when it is taken to an appeal.' (*Reid-Smith v Bristol and Weston*, p. 5, quoting *BP Nursing Home Ltd v East Berkshire*). 'In our view the criterion should be: "what is the most practicable standard (of staffing, of hygiene, of fire precautions, of diet, and so on) which will firstly, provide a reasonable level of safety for residents if a crisis blows up; secondly, will ensure a satisfactory level of service to the patients or residents; and thirdly, do so without laying an undue burden on the staff of the home."' (*Price v Scunthorpe*, p. 9–10). With such aspirations, it can only be hoped that the quality of care in nursing homes does not deteriorate.

Although there is much support for the nursing home inspection process among those who have studied it, it does have clear limitations. First, because the inspection system is administered by the NHS, it can only insist that the quality of facilities in the private sector equal the quality of NHS nursing homes (Hyde 1988). These, unfortunately, do not tend to be paragons of quality. Second, because the units (DHAs) responsible for the inspection process are so small, inspections are normally carried out by part-time staff with substantial responsibilities other than the nursing home regulation. As the homes themselves become larger with more sophisticated legal representation, the regulators may not be able to keep up. Third, until recently standards have focused heavily on structural concerns, and paid little attention to process or outcome considerations, though this may be changing at least in some districts. Finally, as has been noted, the decisions the Registered Homes Act tribunals have offered little support for authorities that insist on more than minimal standards.

Nonetheless, inspection systems undoubtedly make a contribution to

quality assurance. If privatisation of health care institutions proceeds in England, or indeed, in the other countries studied, the lessons learned in nursing home inspection may also prove valuable for creating regulatory programmes to assure the quality of such institutions.

IX. Judicial oversight: medical negligence litigation

It is certainly arguable that the pervasive threat of medical negligence litigation is a primary force driving quality assurance in the United States. First, it has a direct 'deterrent' effect on medical practitioners. Doctors claim in response to surveys, for example, that they perform more diagnostic tests and additional treatments, spend more time with patients, refer more patients to other physicians, keep better records, and consult other doctors more frequently because of the potential of malpractice litigation (AMA 1984; Quam et al 1989).[39] Perhaps even more significantly, the possibility of institutional liability has been a prime motivating factor behind the establishment of institutional risk management and quality assurance programmes. Finally, the threat of institutional liability for negligent credentialing plays a major role in encouraging hospitals to police carefully membership on their medical staffs (Curran 1984; Southwick 1982).

Although civil litigation for medical negligence is possible in England, Sweden, Belgium and the FRG, it is plays a much less significant role in encouraging quality assurance than in the United States.[40] In all four countries the frequency and severity of medical malpractice litigation is much less than in the United States. In England, for example, most regions of the NHS had an annual claim rate of about eight claims per 100,000 population in 1986 and 1987, compared to 29.4 claims per 100,000 in the US in 1984 (Ham et al 1988). Though data are not available on medical negligence litigation from Belgium and the FRG, experts from these countries are of the opinion that claims there are even less frequent. Supporting this belief are data from voluntary pre-trial screening panels in Germany, which almost certainly review more claims than do the courts, and which experience claims rates ranging from 3.53 per 100,000 in Bavaria to 7.25 per 100,000 in Hesse (Bundesärztekammer 1989). Finally, medical negligence litigation in Sweden, which was never very extensive, has now been replaced almost totally by a patient insurance system, which reimburses patients for avoidable injuries caused by medical care.

The disparity between the amounts awarded to claimants by judgment or settlement in the US and in the countries under consideration is even more significant. A 1984 US GAO study, for example, revealed that the mean of all paid claims (involving only one physician provider) for general surgery was $120,889 (£78,000); obstetrics and gynaecology, $177,509 (£114,500); orthopedic surgery, $80,059 (£51,700); and emergency medicine, $22,640 (£14,600). This can be compared to 1986 data from one English regional health authority of mean paid claims for general surgery, £12,700; obstetrics and gynaecology, £3926; orthopedic surgery £10,080 and accident/emergency at £2761 (Fenn and Dingwall 1989).

This disparity in extent and severity of litigation between the United States and the countries here under consideration can be explained by a

number of factors. First, the legal environment is less hospitable to malpractice litigation in Europe than in the United States. None of the four countries countenance contingency fee arrangements (Giessen 1988; Quam et al 1989); thus obtaining legal counsel to gain access to the courts is a very expensive proposition for those not poor enough to qualify for legal aid (Jones 1987; Miller 1986).[41] Those who get to court will not face a jury, as in the United States, but rather a judge, who may well prove a hostile audience (Jones 1987; Miller 1986). In civil law countries the judge will be advised by court-appointed medical experts, who have been criticised for showing bias in favour of the defendant doctor (Dalcq 1985; Giessen 1988). In the FRG and in Belgium, where malpractice is still regarded and prosecuted as criminal conduct, there is a particular reluctance to stigmatise doctors by finding them guilty of malpractice (Dalcq 1985). Finally, in Germany and Sweden negligence claims are unlikely to end up in court in the first place. In Germany pre-trial screening panels, the Schlichtungsstellen and Gutachterkommisionen, established by the state physician chambers, settle much litigation before it gets to court (Deutsch 1985; Giessen 1988). In Sweden malpractice litigation is usually an inferior alternative to a claim for compensation under the patient compensation system (Hellner 1985; Oldertz 1989).

Undoubtedly, however, the most important factor in explaining why litigation for malpractice is less frequent and for lesser amounts in Europe than in the United States is the existence of comprehensive medical and social insurance in Europe and its absence in the United States (Ham et al 1988; Miller 1986; Quam et al 1989). The most obvious effect of this difference is that there is much less reason to sue in countries where the cost of medical accidents will be covered in any event. Young quadriplegic or brain-damaged baby victims of medical malpractice in the US face a lifetime of lost income and high medical expenses, which they must bear personally unless they become eligible for welfare programmes for the poor. Their counterparts in the countries here under consideration would be eligible for comprehensive medical care and social insurance coverage, which would cover most of the 'damages' only recoverable through litigation in the United States.

The existence of social insurance programmes may also effect the propensity to sue in other ways. It is at least arguable that a patient who has not paid directly for medical care will be less inclined to sue when there is a failure of that medical care, and that a patient will be less likely to sue a publicly financed institution than a rich private doctor (Miller 1986; Quam et al 1989). Moreover, the complaint mechanisms available in England and Sweden may make it less necessary for victims to sue to obtain justice or vindication if their financial losses are otherwise covered by social insurance (Miller 1986; Quam et al 1989).

Whatever factors may explain the lesser extent of medical malpractice litigation in the countries examined in this study compared to the United

States, it cannot be attributed to significant differences regarding the standard of care expected of medical personnel by the law of negligence (Giessen 1988). The English articulation of the standard of care in the leading *Bolam* case, for example, reads: 'The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art.' (*Bolam v Friern Hospital*, p. 586 [McNair J], see Brazier 1987). This bears a remarkable resemblance to a typical recent articulation of the standard of care in an American case, *Hall v Hilbun*: 'Each physician may with reason and fairness be expected to possess or have reasonable access to such medical knowledge as is commonly possessed or reasonably available to minimally competent physicians in the same specialty or general field of practice throughout the United States, to have a realistic understanding of the limitations on his or her knowledge or competence, and in general to exercise minimally adequate medical judgment' (p. 871). A similar standard of care obtains in Germany (Deutsch 1985) and in Belgium (Dalcq 1985).

Although judges in European countries may apply these standards more stringently than juries in the United States, the basic message that the law sends to doctors in all countries here under consideration is the same: You must conform to the standard of care ordinarily exercised by colleagues in the same specialty and area of practice; no more, but no less, is expected of you.

While the general paucity of litigation of malpractice litigation in the four countries examined here may muffle this message, other factors at work in some of the countries could potentially amplify it. In most of the countries, hospitals or health services are liable for all or part of the damages caused by doctors practising within them. This is certainly true in the FRG where most hospital-based doctors are hospital employees and where patients commonly join contractual claims against hospitals with their tort claims against the doctors they employ (Deutsch 1985). In Germany patients may also sue a 'Chefarzt' or supervising doctor responsible for supervising the errant doctor. Lawsuits in England have always included the NHS as a defendant, and recently the NHS has proposed accepting full financial responsibility, not only for the faults of its institutions but also for the malpractice of doctors who practise within them (DH 1989c). In Sweden, the county councils, which run the health care system, also end up with financial responsibility for the malpractice of doctors they employ, as they finance the patient insurance system. To the extent, therefore, that malpractice litigation does become significant in Europe, it will create increased incentives for hospitals and health services to supervise more closely the behaviour of the doctors they employ.

In England the medical protection societies, which heretofore have insured hospital doctors and continue to insure GPs, also play an

important role in interpreting the message of malpractice judgments to their insureds. Their quarterly journals, annual reports, and occasional publications contain valuable 'cautionary tales' which attempt to educate their members about conduct that is likely to result in litigation or liability.

The Swedish patient compensation system offers particularly valuable opportunities for using patient claims data to improve medical practice. This system has practically, though not legally, replaced the tort system for dealing with medical negligence.[42] It operates under an arrangement between health care providers, most notably the county councils but also the municipalities and private doctors and dentists, and a consortium of insurers to compensate patients who are victims of avoidable medical accidents (Hellner 1985; Oldertz 1989). The right of the patient to compensation under this system is not dependent on establishing negligence on the part of the doctor or hospital. Rather the patient is compensated for avoidable injuries caused by medical treatment, diagnostic tests, improper diagnosis, iatrogenic infections, and accidents in health care settings. The patient is only compensated to the extent that the injury was avoidable and was caused by medical intervention – unavoidable risks or harm attributable to the underlying medical condition are not compensable. Effectively, the medical provider is held to the highest feasible standard of care, rather than to the minimum as in tort based systems, but liability is still linked to a 'failure' of some kind.

Claims for compensation under the system are presented by patients or by health care providers. Patients are only eligible if they have been more than 50 per cent incapacitated for work for more than 30 days, have been hospitalised for more than ten days, are permanently disabled or have died because of their injuries (Patient Insurance Indemnity Provisions, s. 4). Claims are adjudicated by a patient claims panel, half appointed by the government and half by insurers and providers (Patient Insurance Indemnity Provisions, s. 12) and are appealable to an arbitrator (Patient Insurance Indemnity Provisions, s. 13). Patients are not compensated for losses otherwise covered by Sweden's social insurance system; thus an exceptionally high proportion of compensation, 65 per cent, goes for pain and suffering (Oldertz 1989). In 1987, 4630 claims were reported to the system, about 56 per 100,000 population, high even by American standards. Average total compensation for claims for 1984, the last year for which fairly complete data are available, was only 24,217 SKr, however (about £2400), very low by any standards considering the seriousness of the injuries involved (Oldertz 1989).

Because the Swedish compensation system is primarily concerned with compensation, its administrators are reluctant to get involved in policing medical care, lest they discourage reporting of compensable accidents. They do not, for example, report even egregious instances of medical error to the Medical Responsibility Board. However, they do have a large body

of data on medical error, which they try to use to improve the quality of medical care where this can be done without discouraging claim reporting. Every claim presented to the insurer is reported to the doctor and the chief medical officer of the hospital concerned. County councils are informed of the claims cost for each hospital department which they administer.

A study currently underway is attempting further to analyse adjudicated claims to identify particular avoidable causes of injuries, with the hope of alerting particular hospital departments as to problems they are experiencing and of disseminating more widely through medical journals or conferences information about generic medical failures. If this study realises its potential, it could generate and disseminate directly the kind of information about medical accidents that the tort system produces only indirectly, or perhaps only in theory.

The tort system provides, at least in theory, financial incentives for doctors and hospitals to avoid medical accidents as they experience financial, reputational and, for doctors, personal costs if injuries that should have been avoided occur. While these direct incentives disappear under the patient compensation system, the costs of negligence are still, ultimately, borne by providers, who thus have some reason to learn the causes of accidents and to try to avoid them.

X. The health care system's response: quality assurance and medical audit

The programmes and systems discussed to this point are the traditional tools of quality regulation and have existed in most of the countries under review for decades or longer. As noted in each section, each programme and system is limited in the contribution it can make to quality assurance. In particular, few address the more mundane lapses in quality – those that do not result in the dramatically bad outcomes that in turn result in disciplinary action, complaints or claims. In aggregate, however, these lapses have a significant effect on the quality of health care.

Recently, new forms of quality regulation have emerged under various labels, the most common of which are medical audit and quality assurance, which address a broader range of quality problems. These efforts are often sponsored by professional societies. Some have instead been initiated by individual hospitals, universities, or research institutions. In the very recent past, moreover, some of the countries under review here have begun to mandate such programmes, thus making them regulatory in nature. Belgium, for example, has required hospitals to undertake quality assurance efforts since 1988 (AR, 7 August 1987, ss. 15, 16, 124). The 1988 German health reform law requires quality assurance programmes both in the ambulatory and hospital sector (SGB V ss. 135–137). And the recent British white paper on the health service announces the government's intention to establish medical audit both in primary care and in institutions (DH 1989a; 1989b). This section considers this new phenomena.

England

Quality assurance and medical audit efforts in England are the result of two concurrent, though sometimes conflicting, forces. First, the interest (indeed obsession) of the current conservative government with efficiency, consumer service, strong business-like management, and accountability in the NHS, has led it to mandate quality assurance programmes directed towards assuring that patients get their money's worth (DHSS 1983a; 1989a). Second, the royal colleges (particularly the Royal College of General Practitioners and, more recently, the Royal College of Physicians), the King's Fund, and a number of academic institutions have, as a product of their mission to improve the practice of medicine, initiated a variety of quality assurance and medical audit programmes (Devlin 1988; Pollitt 1987; RCGP 1985a, 1985b; RCPL 1989; RCSE 1989; Shaw 1986b).[43]

Out of these forces have developed a large number and wide variety of projects and programmes that fall loosely into the categories of quality assurance and medical audit. The 1983 Griffiths' NHS management

inquiry, which generally proposed more business-like management for the NHS, found that NHS regions and districts were not paying enough attention to the quality of the product that they were providing consumers (DHSS 1983a). In response to this the DHHS required each region and district to designate a quality assurance officer with a remit to encourage quality assurance programmes. This task was usually assigned to district nursing officers as an add-on to their existing duties.

The derivation of quality assurance programmes from a management concern for consumer satisfaction and their direction by nurses has largely determined their content. Thus quality assurance programmes commonly address the 'shop window' concerns of management or the care delivery concerns of nurses (Adam 1987; NAO 1988; Shaw 1988). Issues often covered include waiting times for operations, waiting times for outpatient clinics, cleanliness, patient comfort, palatability of food, patient dignity and privacy (O'Brien 1987). Medical staff have less commonly been involved in quality assurance programmes, which have, therefore, seldom addressed the technical provision of medical care (Shaw 1987). Quality assurance programmes have until recently been given little direction by the DH or the NHS management board, and have received widely varying levels of support from regional and district management. They have tended, therefore, to be grass roots programmes, which have often duplicated effort and varied greatly in effectiveness. They have often had to proceed with minimal resources, particularly in districts where they have lacked management support. Widespread 'confusion and lack of clarity' continues among district general managers as to what quality assurance is supposed to achieve (Templeton College 1987, p. 13). A recent NHS management directive has provided some guidance. It requires quality assurance systems in all districts focusing, predictably, on appointment systems, informational leaflets for patients, the appearance of public and reception areas, and the use of customer satisfaction surveys (NHS Management 1989).

Despite the obstacles they have faced, these programmes continue to grow in sophistication and number. They have received valuable support from academic and health research centres (Dalley and McIver 1989).[44] Their directors have formed the National Association of Quality Assurance which is coordinating their efforts through conferences, publications and other networking efforts (see NAQA 1988). They are beginning to set standards for services and to evaluate the effectiveness of services in terms of those standards. They are monitoring consumer satisfactions and dissatisfactions through surveys and through complaint review. They are engaged in a wide variety of educational and research activities and are undoubtedly having a positive effect on the quality of patient care.

Professional medical audit programmes, by contrast, are more focused on medical care. The most venerable medical audit programme in England is the Confidential Enquiry into Maternal Deaths in England and Wales,

which has monitored maternal mortality and published triennial reports since 1952. Most maternal deaths during this period have been reviewed by district medical officers, whose reports are reviewed by the regional obstetrics assessor and the Department of Health's central obstetrics assessors. The programme's triennial report analyses causes of avoidable deaths. During the 33-year period covered by the 11 published reports, the maternal mortality rate in England and Wales fell from 989 per million maternities in 1951 to 86 in 1984 (DH 1989d). The Confidential Enquiry into Perioperative Deaths sponsored by the King's Fund and Nuffield Provincial Hospitals Trust and carried out by the Associations of Surgeons and Anaesthetists of Great Britain and Ireland in 1985 and 1986 has undertaken a similar review of deaths caused by surgery (Buck et al 1988; Devlin 1988). This project has now become a national effort in which virtually all surgeons in the United Kingdom are participating (NCEPOD 1989). It has expanded its scope to compare the treatment of patients who die in surgery with similar patients who survive, and to review randomly the treatment of at least one patient per year of every participating surgeon.

Medical audit has also been supported by the Royal Colleges (Shaw 1986b). The Royal College of General Practitioners has strongly supported medical audit among GPs (Pendleton 1986, RCGP 1985b), and has devised a tool for assessing what it identifies as the four most important qualities of GPs: professional values, accessibility, clinical competence, and ability to communicate (RCGP 1985a). The RCGP both audits and requires audit within practices engaged in training of GP trainees. It has also recently initiated a practice activity analysis programme, in which doctors discuss with each other variations in their practice patterns to attempt to become more aware of what they do and why (Crombie and Flemming 1988).

The Royal College of Physicians of London has recently come out with a programme for medical audit and has sponsored several outcome studies on a regional or district level (RCPL 1989). The Royal College of Surgeons has also published an audit programme, which it will use to review training situations (RCSE 1989). Other audit programmes are being carried out on a smaller scale by physicians in individual hospitals or districts (Ham and Hunter 1988; RCPL 1989).

The initiative for medical audit has recently been seized by the government. *Working for patients*, the 1989 health service white paper, mandates the establishment of medical audit in both the hospital and primary care sector by 1991 (DH 1989a; 1989b). The white paper defines medical audit as 'a systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome for the patient.' (DH 1989a, p. 39). It is to be based on confidential physician peer review and directed by the district medical audit advisory committee in the hospital sector and by

a FPC medical audit advisory committee in the primary care sector. Participation will be universal and mandatory, not voluntary as in the past. While medical audit is to be medically led, it is also accountable to management. Management will receive a report on the general results of audit and may initiate an independent audit where it is dissatisfied with a particular service. Initially, responses to poor quality would be corrective and educational in nature but in the long run management might be given more direct means of intervention when quality is inadequate.

Responses in the medical profession to the government's proposal of medical audit have ranged from cautious support to deep suspicion (BMA 1989; Called to Account 1989). The tone of the rest of the white paper, which stresses increased competition within and management control over medical care, and the fact that the white paper follows a long period during which the government has been reluctant to commit additional resources to the NHS, worries even those who generally support medical audit. They are concerned that the requirement of medical audit may bring about additional work without additional resources and also fear management interference with clinical freedom and breaches of confidentiality. Several experts interviewed for this report expressed concern that the government's support of medical audit at this time may discourage rather than encourage support for the concept among doctors.

The debate over medical audit occasioned by the white paper highlights some of the difficulties with establishing quality assurance programmes in the UK. First, the British government, which spends less on health care than any of the other countries here studied, may be reluctant to pay the bill that could result from serious quality assurance efforts. Quality assurance and medical audit can save money, but they can also illuminate the need for additional resources. Some suspect that the reluctance of the government to support hospital accreditation, an idea championed by the King's Fund (Brooks 1989), may be based in part on its reluctance to commit the resources necessary to bring facilities up to accreditation standards. Second, the principle of clinical autonomy is held particularly dearly by British physicians (Harrison and Schultz 1989; Hoffenberg 1986; Miller 1987). Medical audit necessarily allows a doctor to be scrutinised by others, and any form of medical audit, but particularly medical audit accountable to management, will face opposition from many physicians. Finally, the information systems necessary for comprehensive medical audit and quality assurance are still largely absent in the UK. In particular, those 'performance indicators' which are readily available, are criticised for providing little assistance in evaluating health care (Harley 1988; Jenkins 1987). Development of appropriate information will, again, take additional commitment of resources which may not be forthcoming. It will also have to deal with concerns of confidentiality, based, again, on concerns for clinical autonomy.

In sum, there is currently much enthusiasm for quality assurance and

medical audit in the UK and impressive accomplishments can be identified. But achievements are still very uneven, and substantial barriers stand in the way of comprehensive and universal programmes.

The Federal Republic of Germany

The current state of health care quality assurance in the FRG bears some rather striking resemblances to developments in England.[45] In Germany, as in England, two differing traditions of quality assurance have developed historically, one sponsored by professional associations and oriented towards collection and analysis of outcome data, the other sponsored primarily by the payers of care (in Germany, the KVs rather than the government) and designed not to interfere with the clinical practice of medicine. Moreover, the 1988 German Health Reform Act, like the white paper in England, indicates a heightened government interest in physician accountability for the quality of medical care.

Quality assurance in Germany also has a uniquely German flavour. This is most evident in the structure the new law provides for quality assurance, which is to be supervised not by the government but by cooperative efforts of the self-governing organisations of medical providers and insurers. It is also arguably discernable in the traditional focus of quality assurance on technological accuracy.

For over a decade the federal KV (sometimes together with the insurance funds) has issued quality guidelines establishing physician qualifications and technical equipment requirements for a variety of care in the ambulatory sector which it oversees (Flatten 1988; Sachsverständigenrat 1989; Schwartz 1984). Compliance with these guidelines is required if procedures are to be reimbursed by the social insurance system. In several areas these guidelines form the basis for quality assurance review programmes. A few of these are also extended to the institutional sector through joint programmes with the federal physician chamber or by federal law.

Since 1977, the KV has required its members who use their own laboratories for clinical chemistry to participate in 'ring trials', which use external controls to assure the comparability of laboratory results (Beske 1989a; Selbmann 1982). More recently, the KV has begun to require controls through specimens, phantoms, or peer review of pictures for radiology, ultrasound and nuclear imaging. Under recent amendments to the Weights and Measures Act, these measures also apply to the institutional sector. Moreover, quality assurance in radiology is required by recent federal radiology regulations (Bundesärztekammer 1989; Sachverständigenrat 1989). Radiology quality assurance will be supervised by a programme jointly sponsored by the federal KV and physician chamber. The 'Bundesausschusse', or federal committee of the KV and insurance funds, has also issued guidelines for cancer

and children's screening, antenatal care and psychotherapy. The psychotherapy guidelines require second opinions in particular cases (Sachverständigenrat 1989). Further guidelines concerning professional and technical qualifications have been issued by the federal or by state KVs for other areas including nuclear medicine, long-term EKGs, cytology and microbiology (Sachverständigenrat 1989). Finally, the scientific committees of the federal physician chamber have issued a number of recommendations for providing care in various areas, though these are not enforceable through denial of reimbursement, as are the guidelines of the KV (Sachverständigenrat 1989).

The other great tradition in German quality assurance is that of professionally sponsored outcome studies. The most venerable of these is the series of studies in perinatology sponsored by the physician chamber and KV which began in Munich in 1975. The programme currently covers the entire country, with 820 hospitals with an annual rate of about 490,000 births participating (Beske et al 1988; Beske 1989a). The programme documents risks and complications of pregnancy and births, and makes available to hospitals that participate in it biennial hospital-specific and problem-related statistics. Between 1974 and 1986 the rate of perinatal mortality in Bavaria dropped from 26.3 per thousand to 7.1 per thousand (Beske et al 1988). In 1980 and 1984, similar voluntary postoperative studies were carried out in gynaecology, documenting for participating hospitals comparative frequency of complications, pre-operative risk factors, and postoperative morbidity (Beske et al 1988). Studies evaluating the quality of surgical interventions have been carried out in the states of North Rhein-Westphalia and Baden-Wurtemberg (Beske et al 1988; Schega 1984). These studies focus on tracer diagnoses (most commonly, cholelithiasis, inguinal hernia and fracture of the femur) and again provide participating hospitals with comparative process and outcome information. Pilot studies are also being carried out in vascular surgery, neurosurgery, heart surgery, and paediatrics (Beske et al 1988; Sachverständigenrat 1989).

All these studies share common characteristics. Most are sponsored by professional organisations, such as the physician chambers, KVs or the German Surgical Society, and facilitated by academic institutions. Participation by physicians and hospitals is voluntary. Information is collected on a broad basis through relatively simple questionnaires. The identity of patients and doctors is kept confidential. Information as to particular hospitals is revealed only to the chief physician of the relevant hospital department; third parties receive only anonymous data. Department chiefs may use the information however they see fit.

The 1988 German Health Reform Law makes quality assurance mandatory in both the primary and institutional care sectors. Section 135 (SGB V) prohibits payment for new diagnostic and treatment methods under social insurance until such methods have been recognised by the

federal committee of the KVs and insurance funds and these bodies have established professional and technical qualifications and process guidelines for their use. This section mandates the promulgation of guidelines such as the KVs have heretofore promulgated voluntarily. Section 136 (SGB V) goes much further, requiring the KVs to examine in particular cases through sampling the quality of care provided to insureds in ambulatory care, including the choice, extent, and process of treatment. The federal committee of the insurance funds and KVs is to establish guidelines for this quality review.

Section 137 (SGB V) requires hospitals that receive social insurance payments to carry on quality assurance measures. These measures are to address treatment, the course of medical care, and outcomes. Information generated by these measures must permit comparisons among hospitals. Guidelines for these quality assurance measures are to be established jointly at the state level by the associations representing the insurance funds and the hospital owners, and are to address situations in which second opinions are necessary for surgery. Finally, sections 138 and 139 (SGB V) require the KVs and insurance funds to assure the quality and effectiveness of new medical remedies and devices.

Provisions of the new law addressing hospital care build on developments already under way in Germany. Since 1986 the federal medical association and hospital association have had a cooperation agreement for facilitating quality assurance measures. Several cooperative programmes are underway at the Land level, including programmes in North Rhein, Baden-Wurtemberg and Schleswig-Holstein (Beske et al 1989; Sachsverständigenrat 1989). Drafts of agreements among the insurance companies, German hospital association and German medical associations build on these agreements. They contemplate extension of the pre-existing perinatal, neonatal, and surgical quality assurance programmes to all hospitals. The drafts also contemplates further measures addressing the areas of duration of stay, medical records, use of drugs (especially antibiotics and blood products), use of laboratory and radiology, use of invasive or costly diagnostic and therapeutic procedures, operative wound infections, and unexpected results (mortality, complications, readmissions) (Sachverständigenrat 1989). They call for improved data reporting by hospitals, building on requirements established in 1986 that all hospitals report centrally diagnostic data. The drafts contemplate the creation of board of trustees representing the participants in the agreement to review reports of specialists interpreting hospital data, but hold firmly to the principle of nondisclosure of patient, doctor or hospital specific data to third parties.

It is less clear how quality assurance review will be carried out in the ambulatory sector. Comments on the government's initial draft suggested that the quality examination might be combined with the insurance efficiency review system, described in section VII above (Bundesrat 1988).

Experts I interviewed speculated that review might be focused on doctors who are the subject of complaints rather than be carried out on a random basis.

The new law requires the KVs and insurance funds to develop guidelines governing professional practice, which has traditionally been the domain of the physician chambers. As could be expected, the federal physician chamber has strongly objected to this development (Bundesärztekammer 1989).

While these provisions of the 1988 law go further than the laws of any of the other countries covered in this study in mandating quality assurance, they seem to have provoked relatively little controversy in Germany. One expert interviewed, who had followed the development of the 1988 health reform act closely for two years, was unaware before the interview that the provisions were even in the law. It is not difficult to see why this is true. The law on the whole respects the self-governing structure of German health care and makes no radical changes undermining professional power. Quality assurance programmes are to be directed by the medical, hospital, and insurance associations without interference from the government.[46] Confidentiality of review results will continue to be observed. Quality improvement will be achieved through education rather than sanctions. Implementation will proceed slowly, beginning with the development of guidelines at the federal level, followed by the working out of the details at the land and provider level. Everyone interviewed expressed the hope that several years would pass before the law was fully implemented. Quality assurance will remain a function internal to the medical professions, beyond external review.

Belgium

It is difficult for an outsider to assess the current state of medical quality assurance efforts in Belgium.[47] On the one hand, Belgium was the first of the four countries under consideration in this paper to adopt (on 7 August 1987) a comprehensive legal requirement for hospital-based quality assurance. On the other hand, several experts interviewed were of the opinion that little has happened to implement this law, and that the real achievements of quality assurance in Belgium have been at the level of the individual hospital.

As in England and the FRG, the payers of care (here the mutual insurance funds through INAMI) and professional associations can point to achievements in the area of quality assurance. One is the indirect quality assurance effects of the economic review programmes of the insurance funds, discussed in Section VII. Another is the long-standing requirement that the quality of the work done by biological laboratories be externally reviewed before the laboratories may collect insurance reimbursement.

The perinatal monitoring projects of the Vlaamse Vereniging voor Obstetrie en Gynecologie (Flemish Society for Obstetrics and Gynaecology) and the Groupement des Gynécologues de Langue Francaise de Belgique (Grouping of French-Speaking Gynaecologists of Belgium) are important examples of the quality assurance efforts of professional organisations (Buekens et al 1987; Derom et al 1989). These studies involve the confidential collection of data from maternity units, with feedback reports, including profiles, allowing the units to compare their characteristics with those of others. As in Germany and England, participation is voluntary and unit-specific data is not made available to third parties. The Flemish report form includes 65 items and attempts to collect raw data (such as blood pressure or urinary protein levels) rather than diagnostic data to avoid diagnostic inaccuracies or differences of opinion (Derom et al 1989). The French sector data collection procedures differ somewhat, as data in the French hospitals is already computerised, and thus the project need only collate existing data.

In Belgium, as in England and the FRG, the focus of quality assurance efforts has recently changed from voluntary initiatives to externally mandated programmes. As mentioned above, Belgium has had standards governing the physical plant, organisation, and staffing of hospitals, and inspections to enforce these standards, for some time. In 1987, however, Belgium specified, as part of a law restructuring the organisation of its hospitals, responsibilities for quality assurance within each hospital. Effective on 6 May 1988, the head doctor of each hospital is responsible for assuring that 'organizational structures allowing for a systematic process of evaluation of medical practice' exist in his or her hospital (Royal decree, 7 August 1987, arts. 15, 16). A Royal decree of 15 December 1987 further specifies that the head doctor is responsible for keeping records of medical activities and the organisation of medical auditing (s. 6). The Medical Council, which represents the doctors in the hospital, must also ensure that:

'hospital doctors collaborate on suitable measures for:

1) encouraging, and permanently evaluating, the quality of medicine practised at the hospital;

2) promoting a team spirit among the hospital doctors;

3) encouraging collaboration with other members of the hospital personnel and, in particular, with the nursing and paramedical staff;

4) promoting collaboration between the hospital's doctors and other doctors, in particular the general practitioner or the consultant who sent the patient;

5) stimulating medical activity of a scientific nature, having regard to the resources of the hospital.' (AR, 7 August 1987, s. 124).

Department heads are required to cooperate with the head doctor in carrying out quality assurance activities (Royal decree, 15 December 1987, art. 19). Finally, all medical staff are responsible for collaborating in the

evaluation of care, including discussions of policies for admissions and discharges, prescription and distribution of medicines, and medical audit (Royal decree, 15 December 1985, art. 20).

In most respects, the law leaves to individual hospitals the decision of how to pursue quality evaluation. In a few respects, however, the law is more prescriptive. The law sets out in detail the required composition of hospital patient records, and specifies that summaries of these records are to be kept in such a way as to permit the permanent evaluation of medical work. A royal decree of 7 November 1988 requires that hospitals establish hygiene committees to take responsiblity for infection control.

Moreover, the Community Council of Health Care Establishments of the French sector (CCES) has proposed going further, requiring hospitals to conduct medical audit and internal evaluations of staff members and of treatment of patients, and to have ethics committees, committees for the evaluation of nursing care, and multidisciplinary committees for the evaluation of the quality of care (Anrys 1988). The CCES also proposes to create a Central Committee for the Evaluation of the Quality of Care (CEQUAS), which would carry out external audit of hospitals through inspections. CEQUAS inspectors would give technical assistance to the hospitals, but also inform the CCES of the conditions in each hospital relative to the evaluation of the quality of care (Anrys 1988; Roger 1988).

The infrastructure is now being developed within Belgium to effectuate these requirements. For some years minimum clinical information has been centrally collected with respect to hospital patients, and recently nursing information has begun to be centrally collected as well. This data could support external assessment of hospital quality assurance efforts. According to one source, the Ministry of Health has begun to hire inspectors for evaluating the quality assurance programmes of hospitals. The Belgian Federation of Doctors has created an advisory group to assist hospitals in establishing quality assurance programmes and to serve as a clearing house for information on quality assurance programmes.

Nevertheless, it was the opinion of most of the experts interviewed that the real situation in most hospitals in Belgium has not kept pace with the great strides the law has made towards achieving quality assurance. In part this is true because of the inevitable lag between the adoption of laws and the achievement of compliance with them. But more troubling forces are also at work. First, and most important, the new requirements have not by and large been accompanied by new funding.[48] In Belgium, where hospital reimbursement is calculated under a complex formula which considers only enumerated cost items, there is understandable resistance to taking on additional responsibilities not accompanied by new funding. Moreover, the vagueness of the law has left a good deal of uncertainty as to what compliance requires. Some hospitals, for example, believe that hospital-based scientific research activities are sufficient to comply with the law, whether or not they result in changes in patient care.

Within Belgium can be found notable quality assurance programmes at individual hospitals. The nursing quality education and promotion programme of A Jacquerye at Erasme hospital in Brussels is one example (Jacquerye 1987). Another is the quality assurance programme of Dr Gassee at Brugmann hospital in Brussels, which has carried out quality evaluation studies on the use of digoxin, treatment of hand fractures, blood transfusions, and theophylline dosage monitoring. It remains to be seen, however, if and when the universal practice of quality assurance in hospitals, required by the law, will become common practice.[49]

Sweden

In the area of quality assurance and medical audit Sweden has pursued a very different course from the other countries covered by this study.[50] Sweden has not had, as far as could be determined, any national data collections by professional associations such as the studies on perinatal, maternal, or surgical mortality and morbidity found in the other countries. In addition to the medical accident reporting system, discussed in Section V above, the Swedish national government collects data on drug side effects and x-ray utilisation, but otherwise has no national regulatory programmes aimed at quality assurance or medical audit. Most significantly, there is no national legislation requiring quality assurance or medical audit in health care institutions or in primary care.

This is not to say, however, that Sweden has been inactive with respect to quality assurance. Rather, the approach of the government has been to facilitate rather than to mandate quality assurance, trusting in the capacity of the Swedish health care system to do the right thing if it is informed what the right thing to do is. The primary agency of this effort is SPRI, the Swedish Planning and Rationalization Institute for Health and Social Services, which is jointly owned by the Swedish government and the Federation of County Councils (SPRI 1986). A number of other national agencies, including the National Board of Health and Welfare, the Swedish Medical Research Council, and the recently formed Swedish Council on Technology Assessment in Health Care, also contribute towards improving the quality of Swedish health care.

Perhaps the most significant current Swedish initiative for quality assurance (as broadly defined) is technology assessment (also broadly defined). SPRI has over the past decade been involved in a variety of programmes evaluating and setting standards for the use of medical technologies. Its health economics section has produced a number of reports on subjects such as computerised tomography, ultrasound diagnostics, magnetic resonance imaging, care of the elderly, and variations in the use of technology in obstetrics and gynaecology. SPRI and the Swedish Medical Research Council have jointly held several consensus conferences evaluating technologies such as the artificial hip,

care of myocardial infarction, and diagnosis and treatment of cerebral haemorrhage and stroke. During its first year of operation, 1988, the recently formed Swedish Council on Technology Assessment in Health Care undertook nine studies including review of preoperative routines, assessment of treatment methods for back pain, and assessment of the value of vascular surgery for vascular spasms in the legs.

While these programmes are not traditional quality assurance or medical audit programmes, they do contribute to quality assurance. They are not, by and large, narrow technical research programmes, but rather focus broadly on assessing the efficacy, efficiency, and humanitarian and social acceptability of medical procedures, and on making recommendations as to their use. Insofar as they facilitate the introduction and develop guidelines for the use of effective technologies, and deter the introduction of or assist in the elimination of invalid technologies, they make an important contribution to the quality of health care.[51] They may also set the standards for quality assessment programmes, if these are instituted in the future.

Perhaps the most internationally-noted Swedish technology assessment-type initiative has been SPRI's Medical Care Programmes Project (Eckerlund 1986; Pine et al 1988; Vouri 1989). Medical care programmes develop comprehensive standards for the prevention, diagnosis, treatment and follow-up of various health care conditions, adapted to local resources. They tend to focus on treatment of conditions that require primary care over a period of time, in contrast to other technology assessment programmes that tend to focus on particular procedures or on technical equipment. Although these programmes have been acclaimed by some, they have also been criticised as being too complex and too standardised to be of use in the everyday treatment of disease, and for taking too much effort to develop.

Another quality assurance initiative of SPRI is its patient satisfaction survey project (SPRI 1987a). Patient satisfaction surveys developed by SPRI are currently being used in various ways in 68 of Sweden's 80 acute care hospitals. Some of these hospitals compare their results to a large data bank which SPRI has compiled on survey results. It is interesting that England, the only other country included in this study which has publicly provided health care, is the only other country that has extensively used patient satisfaction surveys. Perhaps patient satisfaction surveys compensate to some degree for the absence of a market for health care services in these countries.

Most quality assurance efforts in Sweden, however, take place at the local level, often facilitated by SPRI. The Stockholm informal Health Care Evaluation Group, for example, sponsors a variety of quality assurance programmes within Stockholm County (Reizenstein et al 1987). These projects include study of variations in femoral neck fracture surgery, utilisation of x-rays, and record management. Patient satisfaction with

hospital meals is being followed, as is compliance with medical care programmes for four different diseases. Targeted medical audits and studies of bed occupancy rates are planned or under way. In other counties, SPRI has initiated quality circle programmes. It is currently designing a project to install comprehensive quality assurance programmes in three hospitals.

It is difficult to evaluate the comparative effectiveness of Sweden's non-interventionist approach to quality assurance. It is certainly consistent with the emphases on consensus building and educative approaches to problem solving that characterise Sweden. It also must be placed in the context of Sweden's system of complaint investigation and medical discipline, which provides more extensive external oversight for medical care than is found in any of the other countries studied. Nevertheless, several of the experts with whom I spoke seemed to believe that Sweden was lagging behind in developing quality assurance programmes, that many hospitals were lax in the area of quality assurance, and that the quality of care suffers because of this.

XI. Concluding observations

An American reviewing the current state of quality assurance in the four European countries examined in this report is struck most with the extent to which these countries rely on the medical profession to assure the quality of its member's performance. This is in stark contrast to the United States, which relies increasingly on external controls to assure the quality of medical care. The most obvious example of external review in the United States is medical malpractice litigation, where judges and lay juries assess the performance of the doctors hailed before them. But other examples of external controls come readily to mind: Medicare Peer Review Organisations, which, although run by doctors, are directly accountable to the government for their performance; state physician licensure boards, which increasingly include consumer members and are seen as agencies of state governments rather than as representatives of medical associations; and state and local health departments that inspect medical institutions such as nursing homes and hospitals. Moreover, quality regulation in the United States increasingly relies on sanctions, such as malpractice judgments, delicensure, exclusion from participation in federal health insurance programmes (Medicare and Medicaid) or fines, to police physician performance.

By contrast, the countries studied here still by and large trust the medical profession to police itself. This policing is accomplished largely through educational rather than punitive interventions. This is most obviously true in Belgium, England, and the Federal Republic of Germany, where physician licensure and discipline systems are largely controlled by the medical profession, and malpractice litigation is still, by American standards, relatively infrequent and deferential to medical opinion. Even the complaint systems in England and the insurance review programmes of Belgium and Germany, where these countries come closest to external oversight, are largely under the control of the profession and rather timid in interfering with its prerogatives.

Sweden is a more complicated case. Its Medical Responsibility Board has a higher proportion of lay members than any American licensure board, and its complaint system is also lay run. Lay control may be more apparent than real, however. The lay members of the MRB defer generally to professional opinion. The MRB also generally exercises its power through educational and correctional interventions rather than through delicensure. Sweden effectively has no malpractice system and, in the final analysis, largely depends on medical professionals to assure the quality of their own work and that of their colleagues.

There is, moreover, little apparent interest in Europe in following the United States in its moves towards external control (Pollitt 1987). Recent legislation in the FRG and Belgium and proposed measures in England are largely focused on encouraging more universal peer review rather than on

expanding external oversight. The general goal of these efforts seems to be to improve the performance of the profession by bringing up the average rather than by cutting off the low end tail of the curve. It is based on a belief that professionals will respond more readily to education than to 'fear of the Gendarme'. (Jacquerye 1987, p. 5). Although experts I interviewed often expressed admiration for the peer review systems found in American hospitals, few in the professions, academia, or government had much interest in emulating the American malpractice or PRO systems.

There is much to be said for not blindly following the American approach. First it is proving very costly. The PRO budget for 1990 is $290 million. The cost of medical malpractice insurance in 1985 was $4.7 billion (GAO 1986). The indirect costs of malpractice may be much higher. Moreover, the benefits of external review in terms of better medical care are not immediately obvious. Infant mortality rates are higher in the United States than in any of the countries studied (WHO 1988). Life expectancy at birth for men is lower in the United States than in any of the countries studied except Belgium (WHO 1988). More directly related to medical care, the rate of death in the United States from infectious and parasitical diseases is twice that of Belgium, Sweden and the FRG and three times that of England (WHO 1988). The rate of death from septicaemia in the United States is nearly twice that of Belgium, four times that of the FRG and six times that of England (WHO 1988). One can argue what epidemiological data can tell about the quality of medical care, but it certainly does not establish that American medical care is dramatically better than that in Europe.

Nonetheless, an American observer is left feeling uncomfortable with the European approach to medical care quality assurance for several reasons. First, it is not clear that professional self-regulation can adequately address the problems caused by medical care financing systems that create financial incentives to withhold medical care from patients, and thus a conflict between the pecuniary well-being of doctors and the medical needs of their patients. It was fear of such incentives created by Medicare diagnosis related groups hospital prospective payment that led to the creation of the quality oversight functions of Medicare peer review organisations in the United States (Jost 1988). In none of the countries here studied are such forms of reimbursement yet widespread. In Belgium and the FRG doctors are paid on a fee-for-service basis; in Sweden and England doctors are, by and large, paid a salary. Several countries are considering prospective payment or capitation, however, and several experts expressed the opinion that external review of quality may become necessary if such systems were implemented. Significantly, England's white paper which proposes self-governing hospitals and GP budgets, also proposes management oversight of medical audit.

Second, professional self-regulation has traditionally proved largely

ineffective for removing incompetents from the medical profession, at least in instances where their incompetence did not take forms that publicly embarrassed the professions. Where a doctor could not nor would not deliver medical care of adequate quality because of venality, stupidity, laziness, addiction, or superannuation, colleagues have historically at most responded through ostracism, not by effecting exclusion (Freidson 1973). Although there has been some progress in dealing with substance abuse among doctors in the countries studied, there has been little movement towards dealing with incompetents. The strong hierarchical organisation of hospitals in some European countries (most notably in Germany and to a lesser extent in Sweden and Belgium) may limit the damage done by incompetents, but more needs to be done to identify them and address the problems they cause.

Third, and perhaps most important, there is value in the accountability created by external oversight systems irrespective of whether they actually have a salutary influence on the quality of medical care. Such systems can call doctors to be responsible to society for the resources they consume and for the harm they cause. There is clearly an emerging concern in Europe for some form of medical accountability. It is found in the Medical Responsibility Board in Sweden, in management oversight of medical audit in the white paper in England, in national and French community inspection of medical audit in Belgium, and in the role which the sickness funds are to play in establishing guidelines for quality assurance in Germany. Whether these attempts to create accountability will be adequate remains to be seen.

Perhaps European nations will in the end find some aspects of the American external control approach to quality assurance worth emulating to achieve these purposes. There are certainly also lesson for the United States to learn from Europe. In particular, several countries are further along in devising approaches to quality assurance in the ambulatory sector than the United States, and public complaint systems such as those in England and Sweden should be considered in the United States.

The most important message that can come out of this paper, however, is that European nations have much to learn from each other. National and regional data collections are progressing independently in several countries with little sharing of information and results. Several countries are moving towards medical audit, but with little collaboration. The World Health Organization's Regional Office for Europe has done much to facilitate interest in quality assurance, particularly by bringing together persons interested in quality assurance and by sponsoring quality assurance studies. The International Journal of Quality Assurance, the European Regional Newsletter on Quality Assurance, and the King's Fund Centre's Quality Assurance Abstracts also contribute to this process. The EEC is laying the groundwork for the first Europe-wide data collection effort reviewing ambulatory surgery.

But European countries could do much more to share information and to share ideas. Mutual sharing and development of information could be very beneficial to all countries involved. Multinational data collection efforts, reviewing maternal mortality or perinatal or surgical clinical outcomes, might discover significant variations in outcome among different health care systems, which in turn could ultimately be linked to positive or negative differences in structure or process. Technology assessment might proceed more rapidly and effectively if pursued more broadly on a multinational basis. This seems clearly to be true with respect to assessment of new high-tech equipment, but may also be true with respect to assessment of different approaches to clinical management of medical problems. It is also possible that radiology or laboratory quality review could also be pursued more efficiently on a multinational basis.

There is also much to be gained from sharing of ideas – from Europeans nations learning from examining each others models of quality assurance regulation. England's complaint investigation system, for example, seems clearly inferior to that of Sweden if the goal of a complaint system is to make a health care programme responsible to its patients for failures in delivery of care. The complexity and non-responsiveness of the English system compare unfavourably with the simplicity and responsiveness of the Swedish county confidence boards and Medical Responsibility Board, although the ultimate results in terms of discipline may not be too dissimilar.

Belgium and Germany have led the way in insurance utilisation and quality review. They have much to learn from each other in this area. In particular, Belgium may want to closely observe the participation of the insurance funds and KVs in the implementation of Germany's new health reform law. England may also want to study the experience of the Belgium and German insurance review programs if it proceeds in the direction of turning the health authorities into purchasers rather than providers of health care services. It will certainly need to develop such monitoring systems in such a transition.

The English and West German maternal, perinatal, and surgical outcome data collection programmes can serve as models for other European nations that want a better understanding of the current performance of medical practice in specific areas. The medical incident reporting system of the Swedish National Board of Health and attempts in Sweden to feed back information concerning medical accident claims to the institutions from which the claims originate are both examples of kinds of risk management data collection, analysis and dissemination that all countries could benefit from. The English, in particular, could better use data on the incidence of malpractice litigation in NHS institutions to improve patient care.

The Swedish health care programmes and the guidelines developed by the German federal organisation of insurance doctors for ambulatory care

delivery represent models for standard setting for clinical practice which other countries might want to study. Similarly, the standards designed by some English health authorities for nursing home inspection might be of use to other countries interested in institutional standard setting.

It is not the purpose of this report to design a model system for regulating the quality of physician and hospital care. Neither does it pretend to instruct any particular country in detail as to how to change its systems for assuring medical care quality. Rather it has attempted to describe a variety of models of quality assurance regulatory programmes currently being pursued, with greater or lesser success, by four countries. It is hoped that as readers consider these models, they will see more clearly limitations and opportunities in each model, and that ultimately this report may thereby contribute to the goal of building 'effective mechanisms for ensuring the quality of patient care'.

Notes

This report was written during the winter and spring of 1989 while the author was visiting at the Centre for Socio-Legal Studies, Wolfson College, University of Oxford, funded by a Fulbright Western European Regional Research grant. The author wishes to thank R Dingwall, M Döhler, H Ector, L Muhcahy, C Oldertz, R Schäffer and R van den Oever for helpful comments on earlier drafts; A Wörmer, D Oderberg and K Berglid for assistance with translation; members of the Socio-Legal Centre (especially R Dingwall, P Fenn, D Hughes, A McGuire and L Mulcahy) for encouragement and assistance; the King's Fund for the use of its marvelous library, and all the persons who graciously educated me regarding the health care systems of their countries through interviews.

1. This paper focuses primarily on England rather than on the entire United Kingdom because health care delivery structures and quality assurance systems vary somewhat among the countries of the UK. Where data are available only for the entire UK or for Great Britain or where one system applies throughout the UK (as is true with the General Medical Council) the paper will make clear that the UK or Britain is the basis of reference, rather than England.
2. Parkin et al (1987) argue that a more appropriate comparison of national health care expenditures would take into account the comparative wealth of the country and the comparative purchasing power of units of currency spent on health care. Even by this measure, however, Sweden spends significantly more on health care than the other countries considered here.
3. For an account of the beginnings of the NHS, see Klein (1989) and Webster (1988).
4. Under proposals now being implemented, RHAs and DHAs will be greatly slimmed down in size, brought more under the control of the central government, and focused more on management as opposed to planning (DH 1989a).
5. These too will be trimmed in size and given more direct management responsibility under proposals currently being implemented by the NHS, see DH (1989a).
6. See, on the history of German health insurance, Leichter 1979; Rosenberg 1986.
7. A small public auxiliary fund exists for those who choose not to be members of one of the private funds, as insurance coverage is compulsory and universal.
8. Public employees (railway, post, state institutions, and so on) have their own national disability benefit societies.
9. Hospital-based physician services are reimbursed directly. The physician and insurance company may agree on direct, third party, payment for technical services delivered in an ambulatory setting. Widows, orphans, pensioners and invalids whose incomes fall below a certain level are eligible for 100 per cent reimbursement. On the other hand, doctors in special categories (for example, university professors) or who make special arrangements (no waiting list) can, even within the doctor-sickness fund conventions, charge more than the maximum. There is considerable debate as to the extent to which physicians abide by the maximum fee schedules. It is quite clear, however, that at least some doctors charge considerably in excess of the agreed fee, leaving the patient to cover the difference (Roemer and Roemer 1976).
10. This fee is always at least 2 per cent, for surgeons ranges from 10 per cent to

30 per cent, and can go as high as 80 per cent for some pathologists and radiologists (Roemer and Roemer) 1976.

11. This section is based in part on interviews with V Nathanson, P Towers and Sir J Walton, England; M Döhler and R Schaffer, Germany; and E Borgenhammer and M Timelin, Sweden.
12. Mandatory membership in the Order was challenged as violating the right of freedom of association, guaranteed by Article 11 of the European Convention on Human Rights in *LeCompte, Van Leuven and De Meyere v Belgium*, 43 EurCtHR, Series A (1981) and *Albert and LeCompte v Belgium*, 58 EurCtHR, Series A (1983). The challenge was rejected because the Order is a public law association (and thus not within the purview of the Convention) and because mandatory membership in the order does not preclude membership in other associations. The discussion of the Order which follows in the text is based on Anrys (1971) and interviews with H Nys and H Ector.
13. If a French doctor practises in a Flemish province, or visa versa, he can either be disciplined by his own province, with proceedings conducted through an interpreter, or transferred to the nearest provincial council that uses his language.
14. The deontological code, promulgated in 1975, has never been approved by the King and thus lacks official status. It is, by and large, an explication of the royal decree, however, and has been treated as such by the courts.
15. The private nature of these hearings was challenged as violating Article 6 of the European Convention on Human Rights in *Le Compte, Van Leuven and De Meyere v Belgium*, 43 EurCtHR, series A (1981) and *Albert and LeCompte v Belgium*, 58 EurCtHR, Series A (1983). The challenge was rejected because the possibility of an appeal to the Council of Appeal, which does hold its meetings in public and has jurisdiction to review all questions of fact and law, cures the lack of a public hearing in the first instance.
16. Several of the AKs also have constituent regional or local AKs, which are also public law bodies.
17. These procedures were described to me by R Schäfer. Further information regarding the physician chambers in Germany was obtained from H-P Brauer and F Stobrawa.
18. Doctors informally admonished by the director may also appeal to the disciplinary committee. In an emergency, the president of the AK may notify the Minister of Health of the Land immediately, advising him to suspend a doctor's licence.
19. The discussion of the GMC which follows is based, in part, on discussions with P Towers, J Walton, J Robinson, M Stacey, R Smith, A Simanowitz. For a history of the GMC, see Smith (1989b).
20. This obligation is found in a section of the GMC's blue book, however, entitled Disparagement of professional colleagues, and follows a preceding section threatening doctors who disparage a colleague with discipline.
21. The GMC will help with the expense of this exercise if the complainant cannot afford it, nevertheless, critics of the GMC procedures see this as a substantial barrier for many complainants.
22. The Merrison committee, which comprehensively reviewed the GMC and its procedures in 1975, recommended that investigative staff be retained, but this recommendation was not implemented (see Merrison 1975).
23. See, however, responding to these charges, Towers (1988).
24. The most complete description of the MRB in English is found in Rosenthal (1987). See also Hellner (1985) and Tillinger (1985) discussing the MRB. The description which follows is also based on interviews with I Nygren and N Blum.

25. The German state of Hesse reported 55 disciplinary actions in 1987 and 51 in 1988, during which approximately 20,000 doctors were practising in the state, a ratio of about one action per 375 doctors.
26. The author makes this assertion from his own experience as a lay member of a physician licensure board in the United States.
27. The Deontological Code of Belgium, for example, not only does not require doctors to report professional misconduct of other doctors, but provides 'Doctors always owe each other moral support: they are obliged to come to the defence of a colleague who has been unjustly attacked. It is forbidden to slander a colleague, to speak ill of him, or to repeat anything liable to harm him in the exercise of his practice. A professional disagreement must not give rise to a public exchange' (Art. 136). Article 137 goes on to forbid a doctor from replacing another who has been dismissed or suspended from a public or private institution until he has had contact with the disciplined doctor and the provincial order, to 'ensure that the rules of ethics are respected'. Thus the ethical code stands in the way of other institutions disciplining doctors as well.
28. Summaries of the complaint processes can be found in Allsop (1988); Capstick (1985); Miller (1986); NAHA (1985a); Sinclair (1987). This section is also based in part on interviews with, G Marsh, J Allsop, L Mulcahey, R Klein, P Day, T Richardson and J Robinson.
29. There is no official 'discovery rule', allowing extra time where the complainant did not become aware of the problem until after 8 weeks had run, but the service committee has some flexibility to consider late complaints. A proposal to extend this period to 13 weeks, mooted by the government in 1986, has not yet been implemented, see DHSS (1986). The decision of the administrator not to investigate is appealable to the Secretary of State. See also, with respect to FPC procedures, Allsop and May (1986) and Klein (1973).
30. Procedures described here originate from DHHS Health Circular HC 81(5).
31. The law also provides for formal inquires under HM(66)15 or section 84 of the NHS act of 1977. Hearings under both procedures must be conducted by health authority members chaired by a lawyer. Such formal inquiries have by and large been superceded by the more recent and less formal complaint procedures.
32. In 1987–88, 90 of the 525 complaints investigated by the Health Services Commissioner involved handling of complaints. In 87 per cent of these, the grievance was upheld, HSC 1988.
33. SFS 1980, 12, s. 1. This section is also based on Stockholm Lans Landsting and an interview with Y Fahlstrom.
34. The discussion that follows is based in part on discussions with G Brenner, M Döhler and P Rosenberg.
35. The Vertrauenärztlicher Dienst was under the control of the state pension control authorities and only available to the sickness funds on request. See, concerning the Medizinischer Dienst, Beske (1989b).
36. The following material is based on interviews with F Pratt and R Van den Oever.
37. In England the prescribing pricing authority plays a similar role to the economic monitoring programmes of Belgium and the FRG with respect to GPs. It keeps track of all prescriptions filled at pharmacies and gives all GPs a quarterly (soon monthly) computer analysis comparing their prescribing patterns with those of other GPs in their area and nationally. Physicians whose prescribing patterns are high-end outliers receive more detailed reports and may also receive a visit from the district medical officer.
38. The material in this section is also based on interviews with L Kellaher, A Davis, R Klein and P Day.

39. It is, of course, arguable that doctors have overreacted to the threat of medical malpractice and are now practising 'defensive medicine' which actually harms patients. Evidence that this is so, however, is weak and at best ambiguous. See Quam et al (1989).
40. See generally on malpractice law in these countries, Deutsch and Schreiber (1985) and Giessen (1988). This section is also based in part on interviews with P Fenn, G Hill and A Simanowitz in England; H Nys in Belgium; G Fischer and M Schroder in Germany; and K Oldertz, L Brostrom and C Dahlgren in Sweden.
41. This situation may be in the process of being partially ameliorated in Belgium, where at least one of the large health insurance companies is now, as a service to its members, providing legal counsel to insureds who believe themselves to be the victims of medical malpractice. In Germany health insurance companies may themselves sue to recover the cost of substandard care, Deutsch et al (1985).
42. Outside the patient compensation system, however, employed doctors, nurses and other medical personnel are only personally liable in tort for gross negligence.
43. The discussion that follows is also based on discussions with T Brooks, L Davies, H Devlin, D Flemming, A Gatherer, Sir R Hoffenberg, D Hudson, D Harmon, D MacPherson, R Oliver, V Nathanson, G Rivett and C Shaw.
44. These include Bath University's Centre for Analysis of Social Policy, Birmingham University's Health Management Centre, the Nuffield Centre for Health Service Studies, and York University's Centre for Health Economics. The King's Fund Centre has a special quality assurance project, and publishes a bi-monthly abstract of publications relevant to quality assurance in health care.
45. The material in this section is based in part on conversations with F Beske, H-P Brauer, J Brecht, G Brenner, S Eichhorn, H-K Selbmann, R Sengler, F Stobrawa and K Überla.
46. The Minister of Work and Social Affairs can promulgate guidelines for quality assurance in primary care, however, if the Bundesauschluss fails to do so, SGB V, s. 94.
47. Among useful sources are Anrys (1988) and Roger (1988). This section is also based on interviews with J Blanpain, P Buekens, J Gasse, A Jacquerye and F Roger.
48. Additional funding has been made available for infection control procedures.
49. None of the experts with whom I spoke or the literature I reviewed mentioned quality assurance efforts in the primary care sector in Belgium. A recent draft of an inventory of quality assurance activities in Europe also fails to mention any quality assurance programs in this area (Klazinga 1989).
50. This section is based on interviews with E Borgenhammer, M Brommels, L Cedergren, E Jonsson, C Legerius, G Ljunggren, P Reizenstein and K Roos.
51. A number of other European countries beyond those included in this study are also engaged in technology assessment, including Denmark, Norway, the Netherlands and France (MHSA 1986).

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Table of cases and statutes

Persons interviewed

The following are the persons who were interviewed for this report. All interviews were conducted between January and July of 1989. Most interviews lasted from one to two hours, though a several interviews involved more than one person. I have omitted degrees and academic or professional titles, but all were highly qualified. In addition to names, the primary affiliation relevant to this study and location of the interviewee are listed.

Belgium

J Blanpain, Catholic University of Leuven, Brussels
P Buekens, Free University of Brussels, Brussels
H Ector, UZ Gasthuisberg, University Leuven, Leuven
J Gassee, Brugmann Hospital, Brussels
A Jacquerye, Erasmus Hospital, Brussels
H Nys, Catholic University of Leuven, Leuven
F Prat, INAMI, Brussels
F Roger, Catholic University of Louvain, Brussels
R Van den Oever, National Alliance of Christian Mutualities, Brussels
J Van Langendonck, Catholic University of Leuven, Leuven

England

J Allsopp, South Bank Polytechnic, London
D Brahams, Lancet, London
M Brazier, University of Manchester, Manchester
T Brooks, King's Fund Centre, London
A Davis, Health Services Research Centre, Birmingham.
H Davis, Audit Commission, London
L Davies, Health Services Research Centre, Birmingham
P Day, Centre for Analysis of Social Policy, Bath
H Devlin, CEPOD, Royal College of Surgeons, London
D Flemming, Royal College of General Practitioners Research Unit, Birmingham
A Gatherer, Oxford Regional Health Authority, Oxford
D Harmon, Health Services Research Unit, Birmingham
G Hill, Medical Defence Union, London
Sir R Hoffenberg, Royal College of Physicians, Oxford
D Hudson, National Association of Qualtiy Assurance, Gwent
L Kellaher, Polytechnic of North London, London
R Klein, Centre for Analysis of Social Policy, Bath
D McPherson, Department of Health, London
G Marsh, Health Service Commissioner, London
V Nathanson, British Medical Association, London
R Oliver, Department of Health, London
T Richardson, Oxford Community Health Council, Oxford
G Rivett, Department of Health, London
J Robinson, General Medical Council, Oxford
S Shaw, King's Fund Centre, London
A Simanowitz, Action for Victims of Medical Accidents, London
R Smith, King's College London, London
M Stacey, University of Warwick, Leamington Spa
P Towers, Registrar, General Medical Council, London
Sir J Walton, General Medical Council, Oxford

Federal Republic of Germany

H-P Brauer, German Federal Medical Chamber, Cologne
F Beske, Institute for Health Systems Research, Kiel
J Brecht, Institute for Health Systems Research, Kiel
G Brenner, Institute of the Organizations of Insurance Doctors Cologne
M Döhler, WZB, Berlin
S Eichhorn, German Hospital Institute, Dusseldorf
G Fischer, University of Gottingen, Gottingen
G Griesewell, Ministry for Work and Social Affairs, Bonn
D Poffrath, Health Insurance Institute, Bonn
P Rosenberg, Ministry for Work and Social Affairs, Bonn
M Schroder, University of Gottingen, Gottingen
R Schäfer, North Rhein Physician's Chamber, Dusseldorf
B Schulte, Max Planck Institute of Foreign and International Social Law, Munich
H K Selbmann, Institute for Medical Information, Tubingen
R Sengler, Ministry for Work and Social Affairs, Bonn
F Stobrawa, German Federal Medical Chambre, Bonn
K Überla, Institute for Medical Information Processing, Biometry and Epidemiology, Munich
D Webber, Max Planck Institute for Social Research, Cologne

Sweden

G Berleen, SPRI, Stockholm
N Blum, National Board of Health and Welfare, Stockholm
L Brostrom, Skandia Insurance, Stockholm
E Borgenhammer, Nordic School of Public Health, Gothenberg
M Brommels, Nordic School of Public Health, Gothenberg
L Cedergren, SPRI, Stockholm
C Dahlgren, Skandia Insurance, Stockholm
C Erlo, SPRI, Stockholm
Y Fahlstrom, County Council Complaints Board, Stockholm
E Jonsson, Swedish Council on Technology Assessment, Stockholm
C Legerius, SPRI, Stockholm
G Ljunggren, Karolinska Institute, Stockholm
I Nygren, Medical Responsibility Board, Stockholm
C Oldertz, Skandia Insurance, Stockholm
P Reizenstein, Karolinska Hospital, International Society of Quality Assurance, Stockholm
K Roos, Ministry of Health and Social Affairs, Stockholm
M Timelin, National Board of Health and Welfare, Stockholm

Other

T Casparie, CBO, Erasmus University, Rotterdam
K Johansen, World Health Organization, Copenhagen
G Pinet, World Health Organization, Copenhagen
H Vouri, World Health Organization, Copenhagen

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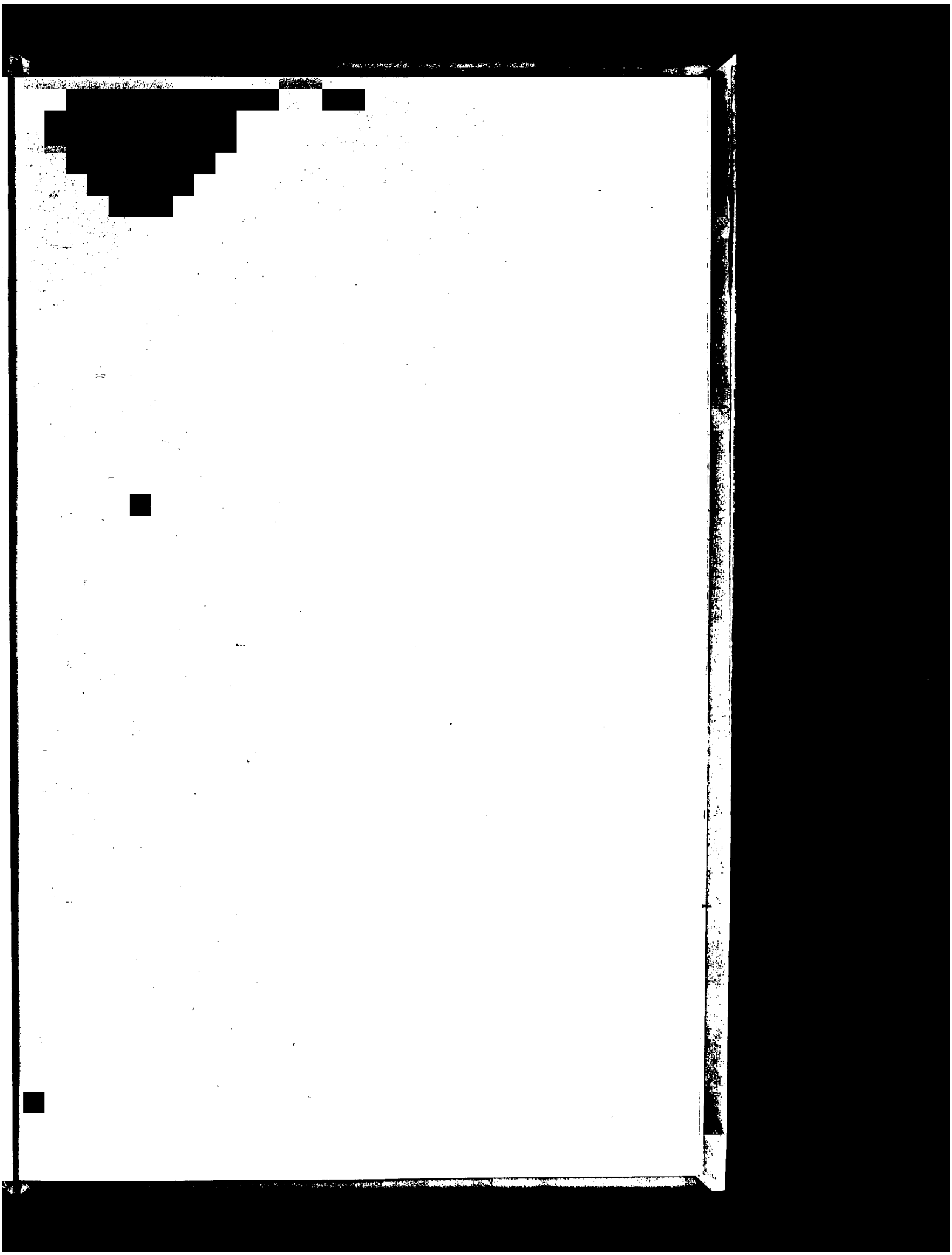

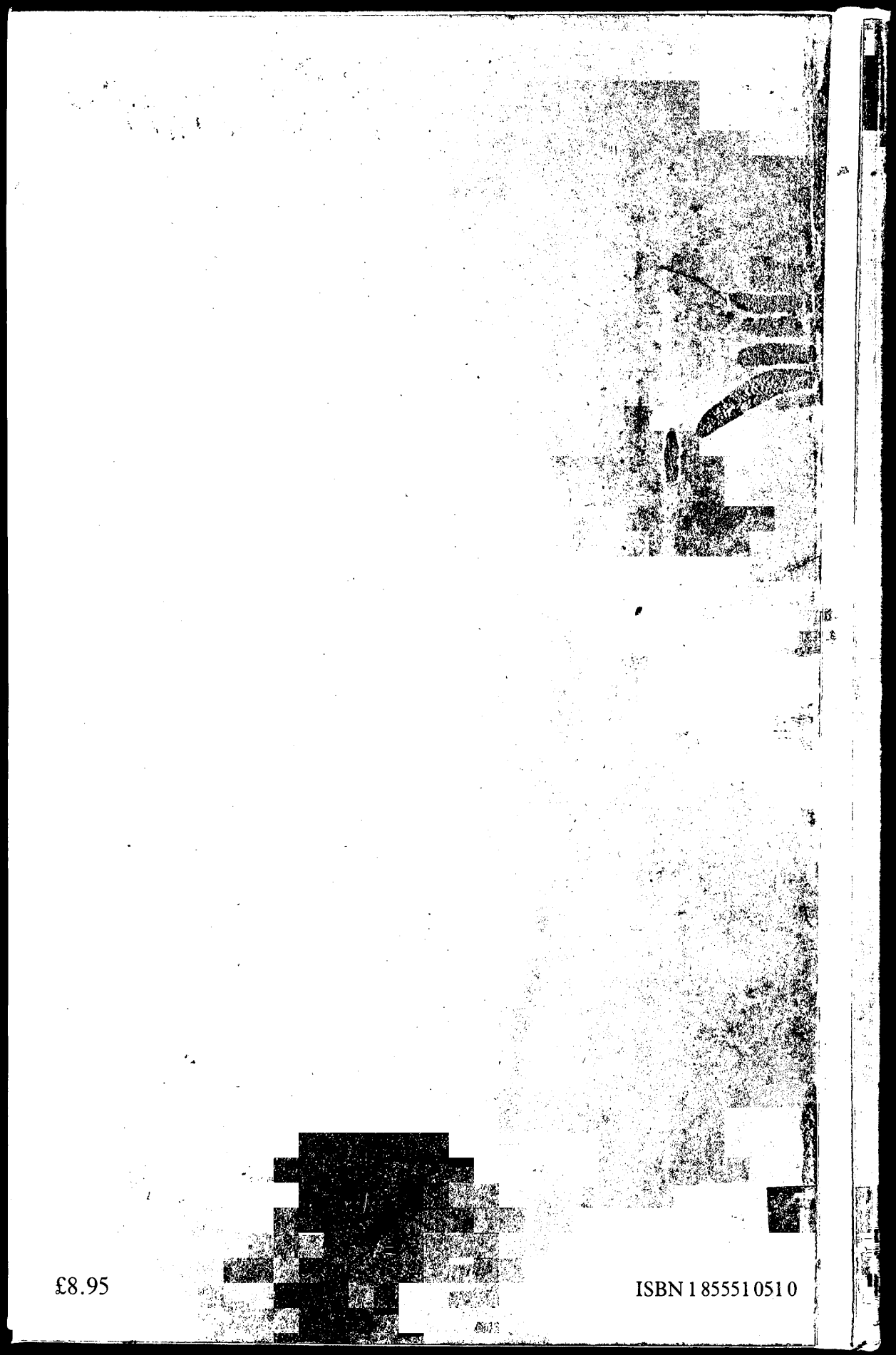

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ISBN 1 85551 051 0